Exhibit C

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            PHILADELPHIA COUNTY COURT OF COMMON PLEAS
                      TRIAL DIVISION - CIVIL
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                          MAY TERM, 2013
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                            No. 003913
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     PATRICIA L. HAMMONS,
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               Plaintiff,
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          VS.
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     ETHICON WOMEN'S HEALTH AND UROLOGY, a Division of
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     Ethicon, Inc.,
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          and
     ETHICON, INC.,
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12
          and
     GYNECARE,
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          and
     JOHNSON & JOHNSON,
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16
               Defendants.
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                     VIDEOTAPED DEPOSITION OF
                     JOYE K. LOWMAN, M.D., MPH
20
21
                         Atlanta, Georgia
22
                     Friday, November 13, 2015
23
24
           Court Reporter: Michelle M. Boudreaux, RPR
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Page 2 1 2 3 4 5 6 November 13, 2015 7 10:22 a.m. 8 Golkow Job No. 117256 9 10 11 Videotaped deposition of 12 JOYE K. LOWMAN, M.D., MPH, held at the 13 offices of Troutman Sanders LLP, Bank of 14 America Plaza, Suite 5200, 600 Peachtree 15 Street, Atlanta, Georgia pursuant to 16 Agreement before Michelle M. Boudreaux, a 17 Registered Professional Reporter in the State 18 of Georgia. 19 20 21 22 23 24	THE VIDEOGRAPHER: We are now on the video record. My name is Josh Coleman. I'm the videographer for Golkow Technologies. Today's date is November 13th, 2015. The time is approximately 10:22 a.m. This video deposition is being held in Atlanta, Georgia, in the matter of Patricia Hammons versus Ethicon, Inc., et al., for the Philadelphia County Court of Common Pleas, Trial Division. The deponent is Joye Lowman, M.D. Counsel will now please identify themselves for the record. MR. SLATER: Adam Slater for plaintiff. MR. GOODALL: Jon Goodall for plaintiff. MR. ISMAIL: Tarek Ismail for the defendants. MS. DEMING: Kay Deming for the defendants. THE VIDEOGRAPHER: The court reporter is Michelle Boudreaux and will now swear in the witness.				
Page 3 1 APPEARANCES OF COUNSEL 2 3 On behalf of the Plaintiff: 4 ADAM M. SLATER, Esq. (via videoconference) Mazie Slater Katz & Freeman LLC 5 103 Eisenhower Parkway, 2nd Floor Roseland, New Jersey 07068 6 973.228.9898 aslater@mskf.net 7 JONATHAN GOODALL, Esq. 8 Kline & Specter, P.C. 1525 Locust Street 9 Philadelphia, Pennsylvania 19102 215.772.1000 10 jonathan.goodall@klinespecter.com 11 On behalf of the Defendants: 12 TAREK ISMAIL, Esq. 13 Goldman Ismail Tomaselli Brennan & Baum LLP 564 West Randolph Street 14 Suite 400 Chicago, Illinois 60661 15 312.681.6000 tismail@goldmainsmail.com 16 N. "KAY" KAREN DEMING, Esq. 17 Troutman Sanders LLP Bank of America Plaza, Suite 5200 600 Peachtree Street, N.E. Atlanta, Georgia 30308-2216 19 404.885.3000 karen.deming@troutmansanders.com 20 21 Videographer: Josh Coleman 22 23 24	Page 5 JOYE K. LOWMAN, M.D., MPH, being first duly sworn, was examined and testified as follows: EXAMINATION BY MR. SLATER: Q Dr. Lowman, good morning. A Good morning. Q I'm Adam Slater. I'm here to take your deposition today. You've been named as an expert witness. You understand you've been put forward as an expert witness for Ethicon and Johnson & Johnson in this case? A I'm yes, I'm counseling I am a consultant with Troutman and Sanders, yes. Q You're a consultant with Troutman and Sanders. Do you understand that you've been named as an expert witness for Ethicon and Johnson & Johnson in a litigated case in Philadelphia County? A I understand that I'm an expert witness, yes. Q Have you ever been an expert witness in another case before this? A I have not. Q Okay. You understand you're under oath now, right?				

Page 6 Page 8 A I understand that. My understanding of your 1 A The summer of 2015, yes. 1 2 question is have I served as an expert witness. I've 2 When did you first have any discussion with 3 served as a fact witness. I don't know if there's --3 anybody or receive any information with regard to the 4 4 I'm assuming that there's a difference there. Hammons case? 5 Q There is. We'll talk about that later. 5 Again, I don't remember that exact date, but 6 You understand you're under oath and must 6 I believe it was also in the summer as well. 7 tell the truth in response to every question I ask you, 7 Q Summer of 2015, correct? 8 8 correct? A Of 2015. I think it was around August, but 9 9 A Correct. I'm not sure. 10 Q Okay. If you have a question about something 10 O Is this case the first time you've acted as that I ask you or anyone else asks you -an expert witness in a litigated matter? 11 11 A Uh-huh. 12 12 A Yes. 13 -- because the question is unclear to you for 13 Have you ever been deposed before? Q some reason, just tell me or whoever is asking you the 14 14 Α question so that we can clarify what it is that you 15 15 Q How many times? don't understand, okay? 16 16 Once before. Α Q Do you remember the name of that case? 17 A Okay. I thought I understood the guestion, 17 18 but I'll make sure that I clarify, uh-huh. 18 A I -- the patient's name? 19 Q I'm just telling you in the course of the 19 Q Anything about the name of the case. deposition, for example, I may ask you about medical 20 20 A I remember the patient's name, yes. 21 terminology that I don't understand. I may 21 Q Okay. What was it? mispronounce a word. I may ask you something that 22 THE WITNESS: Am I allowed to disclose 22 23 makes no sense to you whatsoever because I mumble --23 that? 24 A Right. 24 MR. ISMAIL: You are. Page 7 Page 9 1 Q -- or because I'm tired or I can't get my 1 MR. SLATER: Yes. 2 2 sentences put together. Whatever the issue is, if you THE WITNESS: Okay. 3 don't feel comfortable answering the question because 3 MR. SLATER: Yes. 4 you don't understand what you're being asked, just ask, 4 THE WITNESS: Annette Lucas. 5 you know, for clarification on what seems unclear, 5 Q (By Mr. Slater) Were you deposed as a 6 okay? 6 treating doctor in that case? 7 Okay, not a problem. 7 Α A I was. 8 There will be objections during the course of 8 O What are the fees that you're charging for the deposition. I don't expect that there will be 9 9 your work in this case? 10 substantive objections, but you may hear "objection to 10 A I'm charging 400 an hour and 600 an hour for 11 the form of the question" sometimes. That's not a 11 deposition and trial. signal and it's not anything that you should be 12 MR. SLATER: What I'd like to do -- I 12 distracted by. Lawyers do that because they want to 13 13 think we've marked as Exhibit 1 Dr. preserve their rights under the evidence rules at 14 Lowman's expert report and the materials times. So just let somebody state their objection and 15 attached to it. So if we could, let's -- if 15 16 then answer the question after the objection, okay? 16 we could hand that to her, I'd appreciate it. 17 17 Q (By Mr. Slater) Dr. Lowman, you've had put Α Okay. 18 Q When were you first contacted to do work in 18 in front of you what we've marked as Exhibit Lowman 1. 19 Tell me what that is. 19 this case? 20 A I don't remember exactly. Karen reached out 20 It's my expert report. to me at some point during the summer about possibly Q When did you write this report? 21 21 consulting with them about cases like this, but I don't 22 22 I don't remember the exact date. 23 remember the exact date. 23 And we'll start with this: You didn't write 24 The summer of 2015? 24 it yesterday, right?

Page 10 Page 12 Q Do you know Dr. Raders, who works with 1 A I didn't write it yesterday, that's correct. 1 2 Q All right. Well, tell me -- tell me what 2 Dr. Zipper? 3 3 A I have met Dr. Raders before, yes. month you wrote it in. 4 Did you work with him in Pennsylvania? Was 4 A I think it was September. 5 O September of 2015? 5 he with Dr. Lucente at that point, or had he left by 6 6 then? A 2015, yes. 7 Q Does this report contain each of the opinions 7 A He was with Dr. Lucente at that point. 8 that you formed in connection with this case? 8 O What was Dr. Raders' role or what was his 9 9 A It does. position at the time that you knew him in Pennsylvania? A I don't know his position specifically. My 10 In the course of the report, you discussed 10 certain facts, both general facts about the Prolift and understanding is that he was training under 11 11 about the medical literature, as well as about Dr. Lucente. 12 12 Ms. Hammons in specific. 13 0 Do you know Dr. Weber? 13 A I've never met her, but I am -- I've heard 14 A Yes. 14 her name before, yes. 15 Did you set forth and discuss those facts 15 Q You know who she is, correct? that you felt were most important to you in forming 16 16 17 A I've seen her name on several publications, 17 your opinions? A Did I spell out the facts that were most 18 but I've never met her. 18 important to me? I believe I did, yes. 19 Q Do you know Charlotte Owens? 19 20 Q This report is 58 pages long and it's dated 20 A No. August 2015, correct? 21 21 Q Do you know who Charlotte Owens is? 22 A Yes, not including the appendix, my part of 22 A I don't know. That name doesn't ring a bell, 23 the report is 58 pages long. 23 no, but I'm bad with names, so I can't say that I've 24 24 Q Did you write this report yourself, every never met her. I just don't know that person. Page 11 Page 13 word of it? 1 Q My question is: Do you know who Charlotte 1 2 2 A I wrote this report myself. Owens is? 3 3 Q Nobody else had any input into writing this A No. 4 report? 4 Q Robinson is? 5 5 MR. ISMAIL: Objection. Are we getting A I'm sorry? 6 into drafting of the report? 6 THE WITNESS: He's coming in and out. 7 MR. SLATER: I'm not asking if -- who 7 Q (By Mr. Slater) Do you know who David 8 Robinson is? 8 was involved or what involvement anybody else 9 A I don't believe so. 9 had. I just want to understand whether 10 10 Do you know Pete Hinoul? Dr. Lowman wrote every word in this report 11 herself. 11 Α Could you repeat that? 12 Sure. Do you know Pete Hinoul? 12 THE WITNESS: Yes. Q Q (By Mr. Slater) Doctor, when you wrote this 13 13 Α No. report, did you look at other reports to see what the 14 14 H-I-N-O-U-L. report was supposed to look like for format, for 15 H-I-N-O-U-L. No, I don't. 15 16 example? 16 Q Do you know who Pete Hinoul is? 17 A In writing the report, I reviewed other 17 A I don't. expert reports, yes. I'm not sure if I understand the 18 Q Do you know who David Robinson is? 18 19 You just asked me that, I think. No. 19 question. 20 I thought I asked you if you knew him. I Q What other expert reports did you review? 20 21 just wanted to ask you, do you know who David Robinson 21 A I reviewed Dr. Zipper's report and I reviewed Dr. Weber's report. 22 is? 22 23 A I don't think so. 23 Do you know Dr. Zipper? Q I don't. 24 Do you know who Scott Ciarrocca is? 24 Α

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	Page 14		Page 16
1	A That name doesn't ring a bell either.	1	MR. SLATER: Okay.
2	MR. ISMAIL: Did you ask a question?	2	MS. DEMING: Unless it's our you
3	Q (By Mr. Slater) Do you know Paul Parisi?	3	know, the guy that's in charge of our all
4	A Paul Parisi. I don't think so.	4	video stuff that will make sure that it's
5	Q Do you know who Scott Ciarrocca or Paul	5	coming through and everything is goes kosher
6	Parisi are?	6	here, he'll check periodically, but other
7	A No.	7	than that, no.
8	Q Do you know who Price St. Hilaire is?	8	Q (By Mr. Slater) Doctor, attached to your
9	A No.	9	report is an Appendix A. Can you turn to that, please?
10	Q Do you know who Axel Arnaud is?	10	A Okay, I'm here.
11	A I don't. I've seen that name in some of the	11	Q It says "Curriculum Vitae" with your name.
12	expert reports, but I don't know who that person is.	12	Is that what this is?
13	Q Do you know who Jim Hart is?	13	A Yes, that's part of it, uh-huh.
14	THE WITNESS: What did he say? Jim	14	Q It says that you did your residency in
15	did you say Jim Hart?	15	obstetrics and gynecology at Abington Memorial
16	MR. SLATER: Yes.	16	Hospital.
17	THE WITNESS: No.	17	A Yes.
18	Q (By Mr. Slater) In preparing your report,	18	Q Is that correct?
19	did you read the deposition transcript of any witness	19	A That's correct.
20	employed by Ethicon?	20	Q Who trained you at Abington?
21		21	A Oh, my gosh. A number of different
22	A Did I read the deposition transcript of any witness employed by Ethicon? No.	22	physicians were involved in training us there.
23	· · · ·	23	Q Great. Tell me who they were.
24	Q In preparing your report, did you read the deposition transcript of any deposition taken of	23 24	A I can't list I mean, it was, I think, 10
27	deposition transcript of any deposition taken of	27	A 1 carrellse 1 mean, it was, 1 tilling, 10
	Page 15		Page 17
1	Dr. Vincent Lucente?	1	groups, different private practice groups, so I can't
2	A No. We can't hear you.	2	list all of them. I don't remember all of their names.
3	Q Read any deposition or	3	Q Were you trained by Vincent Lucente?
4	THE WITNESS: He's coming in and out.	4	A Dr. Lucente was one of them, yes.
5	MS. DEMING: Well, actually, it's just	5	Q Tell me about the training Dr. Lucente did
6	the delay in the video.	6	with you.
7	THE WITNESS: Oh, it's a delay. Oh.	7	A Dr. Lucente was the I don't know the
8	MS. DEMING: So his question will	8	formal name for it, but he was over our urogynecology
9	actually ultimately get to you.	9	training, so he provided that aspect for us. We have
10	THE WITNESS: Gotcha.	10	to be exposed to all of the surgical subspecialties,
11	MS. DEMING: But it's looking different	11	and he was the person that did that for our residency
12	on the camera.	12	program.
13	THE WITNESS: Okay. Sorry.	13	Q What did the training that Dr. Lucente gave
14	Q (By Mr. Slater) Any deposition transcript or	14	you consist of?
15	testimony given by Miles Murphy?	15	A It consisted of didactics and operating room
16	, 5 , ,	16	experience, as well as office you know, he would
		17	· · · · · · · · · · · · · · · · · · ·
17	MS. DEMING: I just misspoke.		oversee us seeing patients that came with
18	Sometimes, Adam, you're beginning a question,	18	urogynecologic problems to our clinic. We had a
19	but it's not coming in over the microphone.	19	resident clinic, and he would oversee patients that had
20	So she's getting sort of the back end of your	20 21	problems with urogynecology.
21	question.		Q Other than general training in the residency
21	•	วา	for uroavnocology, did you do any other work with
22	MR. SLATER: There's no bridge on this,	22	for urogynecology, did you do any other work with
	•	22 23 24	for urogynecology, did you do any other work with Dr. Lucente? A At one point, we were trying to do some

Page 18

research together. I don't remember the specifics of it at this point. But other than that, no.

Q What type of research was it?

A I don't remember. It was so along ago and it never really got anywhere because Dr. Lucente was so busy at the time, so I honestly don't remember.

Q You don't remember anything about the research at all?

A No. I just -- I just --

Q Nothing that you can tell me?

A I don't. I remember that as a resident, we had to do a thesis research project, and I wanted to do my project within the field of urogynecology, so I remember us talking about that, but we just weren't able to really get anything together. So my project ended up being on magnesium sulfate prophylaxis in hypertensive disorders in pregnancy. So I honestly don't -- I don't remember what we talked about.

Q Other than being the head of the urogynecology training during your residency, did Dr. Lucente have any other involvement with your education?

A Not with direct education. He did write a letter of recommendation for me and going to -- when I

Page 20
A I misspoke. What I meant to say was I was

trying to get some greater perspective on

3 Dr. Zipper's -- on his opinions, where that was coming 4 from.

5 Q When you say you wanted better perspective on 6 Dr. Zipper's opinions, does that mean you told

7 Dr. Lucente what Dr. Zipper's opinions were and asked

8 him --9 A No --

Q -- his thoughts?

A -- I did not. No. What I wanted to do was to understand why someone who has actually used mesh for pelvic reconstructive surgery was now so against its use. My exposure and experience up until that point had been with physicians who were nonmesh users who thought very negatively about mesh. And I understood that perspective because they see some of the complications and don't get the benefit of seeing some of the successes. So I understand their perspective.

I was surprised by Dr. Zipper's perspective, and I wanted to speak with Dr. Lucente about whether or not he had any understanding that might make that more -- that might make it make sense to me.

Page 19

was trying to pursue fellowship. I don't know if you would consider that a part of my education.

Q Have you spoken with Dr. Lucente at all about this litigation, either this case in specific or general mesh litigation?

A I have.

O When was that?

A I don't remember exactly. It was within the last three months for sure because I remember wanting to speak with him specifically about Dr. Zipper's report, or about Dr. Zipper, I should say.

Q You spoke with Dr. Lucente within the past three months?

A Yes.

Q And you spoke to him about Dr. Zipper?

A I wanted to. I couldn't remember -- like I said, I'm bad with names, and so when I actually spoke with Dr. Lucente, I couldn't remember Dr. Zipper's name. But the goal of the conversation for me was to try to get some better perspective on Dr. Zipper.

Q You originally said that you discussed

22 Dr. Zipper's report with Dr. Lucente.

A Right.

Q Tell me about that.

Q What did Dr. Lucente tell you?

A He just, you know, sort of lamented the fact that that is the current situation, that there are some people that feel that way. Again, I couldn't remember Dr. Zipper's name and I don't know who Dr. Zipper is. So he just sort of gave some general opinions about the fact that that's the way it is.

O Tell me what he said.

A Oh, I don't -- I don't remember exactly what he said. Like I said, it was three months ago or sometime over the past three months.

Q Did you consider this an important conversation when you spoke to Dr. Lucente about the work you were going to do in this case where you were going to be an expert witness?

A What do you mean by did I consider it an important conversation? It was just a conversation --

Q I'm trying to figure out -- I'm trying to figure out why it is that you're having trouble recalling things that I'm asking you, because my guess is that you'll have recollection of things that are favorable to the position that you've been hired to defend.

24 A No, that's not true.

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Page 22 1 So I'm trying to get at why you're having 2 trouble. 3 Α Yeah. 4 Q I'm sorry, but I was talking. 5 Α Okay. 6

I'm trying to figure out why you're having such trouble recalling things that I'm asking you about.

A Because --

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MR. ISMAIL: Objection. Move to -sorry. Objection to form. Move to strike the attorney commentary.

THE WITNESS: You're asking me specifics about a conversation that was just a regular conversation that I wasn't thinking, oh, this is something that I should be able to tell somebody about three months from now. This was a conversation that I had with somebody that I consider to be a friend and colleague that I -- had nothing to do with any specifics of this case.

If you asked me a -- what conversation I had with my mom two days ago, I wouldn't be able to recount to you exactly what we said.

my opinions about the Prolift. It's not just 1 2

Dr. Lucente. But did I consider his data, yes.

Q Was Dr. Lucente's -- well, rephrase.

Is Dr. Lucente's data and the things that he has written and said about the Prolift, the things you're aware of, is that an important part of what you rely on? I understand you rely on multiple things, but is that an important part of what you rely on?

Page 24

A It's part of what I rely on, yes.

10 O Would you consider it to be an important part 11 of what you rely on?

A Not any more important than any of the other literature that I considered, no.

Have you ever been paid money by Ethicon?

15 Α No.

16 Q Other than as an expert witness?

Α

18 Q Have you ever worked on a study where Ethicon 19 paid money for the study to be performed?

A We did a study on the Prolift, an MRI study, when I was a fellow with Dr. Hale, and Dr. Hale was involved in securing some funding to be able to perform the MRIs.

Q Were you ever given any nonfinancial benefits

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I can tell you the general gestalt, but I 1 2 cannot tell you exactly what was said.

Q (By Mr. Slater) You consider Dr. Lucente to be a friend?

A Absolutely.

Q You consider Dr. Lucente to be a colleague?

A I do.

Q Do you -- do you respect Dr. Lucente's research in the field of pelvic surgery and particularly with regard to the Prolift?

A I do.

Q Do you think that Dr. Lucente's literature with regard to the Prolift is something that's important to consider in forming your opinions?

A I do.

Q Has anybody ever indicated to you that there were any questions about the validity of the data reported by Dr. Lucente in any of his studies?

A No.

Are the findings that Dr. Lucente has made in the medical literature and the things that you've learned from him important to you in forming your opinions about the Prolift?

A All of the data is important to me in forming

Page 25 1 by Ethicon, for example, meals or travel expenses being 2 paid, anything like that?

A I don't remember specifically. I know that -- I think that I may have attended a training session, and sometimes they do reimburse for travel and meals when you attend training sessions. So they may have.

Q Have you ever signed a consulting agreement or any type of an agreement with Ethicon to perform any work on behalf of their professional education or marketing department where they would agree to pay you for what you did?

A No.

Q Have you ever acted as a proctor or a preceptor for a Prolift procedure where you've been involved in demonstrating for other doctors how the -how the Prolift is performed?

18 A Not where -- not where -- not being paid, no. 19 When I was a fellow, we would sometimes --

Q Well, how about --

21 A When I was a fellow, we would sometimes train 22 residents on some of the procedures that we were 23 performing, but I have not trained other physicians for 24 payment, no.

Page 26 Page 28 Q Have you ever been involved in a proctorship Q You had spoken with Dr. Lucente? 1 1 2 or a preceptorship where physicians watched a procedure 2 MR. ISMAIL: Restate your question, 3 that you performed, whether or not you were being paid? 3 please. 4 And I'm talking about Prolift procedure. 4 Q (By Mr. Slater) What was the context that 5 A No. 5 you spoke to Dr. Lucente in -- the last time you had 6 6 Q Have you ever been involved in a proctorship spoken to him before you spoke to him about Dr. Zipper? 7 or a preceptorship that was sponsored by Ethicon where 7 A I don't remember. It had been a long time they were going to bring doctors to see you operate? 8 8 since we actually spoke. I -- unfortunately, we're all 9 9 very busy and so we don't often, you know, talk as much 10 Q Were you ever involved in planning an event 10 as we'd like, maybe. I don't speak with him on the 11 11 where you were going to either participate in a phone regularly. 12 proctorship or a preceptorship where Ethicon was going 12 Q What procedures do you currently utilize to to sponsor the event and bring doctors to see you 13 treat anterior prolapse or cystocele? 13 14 perform a procedure? 14 A The -- most often an abdominal 15 A I don't believe so. Not that I can remember. 15 sacrocolpopexy. 16 Q You currently would use abdominal 16 Q Have you interacted over the years with 17 Ethicon employees? 17 sacrocolpopexy to treat a cystocele? 18 A Yes. 18 A If -- yes, if it's a significant cystocele 19 MR. SLATER: I'm sorry, are you guys not 19 and I'm -- that I think requires surgical treatment, 20 hearing me? 20 that's my procedure of choice, yes. 21 MR. ISMAIL: No. 21 Q Do you perform anterior colporrhaphy? (By Mr. Slater) I asked who, which Ethicon 22 22 Α 23 employees have you interacted with? 23 Q Have you performed anterior colporrhaphy with 24 A Oh, I don't remember. Most of that was 24 sutures in your practice? Page 27 Page 29 during my fellowship, so I -- again, I'm bad with 1 A I have. 1 2 names. I don't -- I don't remember their names. 2 Q Do you perform abdominal sacrocolpopexy on a 3 Q What did those interactions involve? 3 patient where they have a cystocele but no vaginal 4 4 vault prolapse? A Sometimes the reps would come to the 5 5 A It's unusual to see that. But if I had a operating room to make sure that we had the products 6 that we needed. I remember interacting with someone 6 patient who had a significant cystocele, I would recommend an abdominal sacrocolpopexy even in the 7 when I was preparing my Prolift paper for presentation 7 8 8 at the Society of Gynecologic Surgeons because I needed absence of apical prolapse. 9 an electronic picture. I don't remember any other 9 Q What is a significant cystocele? What does 10 specifics. 10 that mean? 11 Q Have you ever spoken with Dr. -- well, let me 11 A A cystocele that's symptomatic. Sometimes ask you this. Let me take a step back. You said you 12 12 patients are referred to me because they have a 13 spoke with Dr. Lucente in the last three months about 13 cystocele but the patient is not actually complaining Dr. Zipper, correct? of anything or the cystocele is not bothering them. If 14 14 it's just there, then it doesn't require treatment. 15 A That's correct. 15 16 Q How long was that conversation? 16 But if the patient is actually bothered by the 17 A Very brief. If I had to guess, maybe three 17 cystocele, then I would recommend an abdominal minutes, three, four minutes. 18 sacrocolpopexy. 18 19 Q Have you spoken to Dr. Lucente since that 19 Q So the extent of surgery you would perform

8 (Pages 26 to 29)

would be dependent not just on the anatomic findings,

In terms of evaluating the success of a

but also on the clinical symptoms reported by the

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patient?

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Correct.

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time?

A I have not.

Dr. Lucente before that?

Q When was the last time you had spoken to

A It had been quite some time. Months.

Page 30 Page 32 prolapse repair surgery, do you agree that the Q Is that of any significance to you in forming 1 1 2 functional outcome in terms of how it -- how the 2 your opinions in this case, what Ethicon internally 3 3 patient is functioning day to day is more important believed? 4 than the anatomic outcome? 4 A No. 5 Α No. 5 Do you know anything about the criteria 6 Q Literature and statements by professional 6 applied by Ethicon in deciding whether or not the 7 organizations to that effect? 7 Prolift should be put on the market in 2005? Do you 8 A I'm sorry, you dropped off for a second. Can 8 know what criteria they applied? 9 you repeat the question? 9 No. Α 10 Q Are you familiar with statements by medical 10 0 Did you ask the attorneys who retained you to societies and/or medical literature indicating that get you any information about the criteria Ethicon 11 11 functional outcomes should be the primary measure for applied when deciding whether or not the Prolift should 12 12 whether or not a prolapse procedure has been successful 13 be marketed? 13 14 14 Α No. 15 Q 15 A I'm aware of literature that says that Was that of any significance to you at all? functional outcomes should be considered. Whether or 16 Α 16 17 not it's more important, I'm not aware of that, no. 17 Do you know what Ethicon knew internally, Q 18 Q In determining whether a -- rephrase. 18 outside of what is in the published medical literature 19 In determining whether a prolapse procedure 19 or literature that you've seen at meetings, with regard 20 has been successful, you would not just look at the 20 to the risk-benefit profile of the Prolift? 21 anatomic outcome, correct? 21 Α No. 22 A That's correct. 22 Q Was that of any significance to you? 23 Q In determining whether a prolapse procedure 23 Α 24 was successful, you would look at the functional 24 Q Do you know who Bernard Jacquetin and Page 31 Page 33 outcome in terms of how the patient is doing and how 1 Michelle Cosson are? 1 2 they feel, as well as the anatomic outcome in terms of 2 A I've read their names in the literature. 3 how the organs and how the vagina looks, correct? 3 I've never met them. 4 A Yes, but more specifically the symptom that 4 Q Do you know what role they played with regard 5 relates to that anatomic outcome would be the thing 5 to the Prolift? 6 that I'd be most interested in. 6 A Yes. 7 Q I think what you're saying is, if you saw, 7 MR. GOODALL: Adam, we didn't hear that 8 8 for example, after a cystocele repair, that the patient question. had a second-degree cystocele eight months later but 9 9 (By Mr. Slater) As to the role that Bernard was -- said, "Oh, I feel a little bulge, but it's not 10 Jacquetin and Michelle Cosson played with regard to the 10 11 really bothering me," would you feel that that surgery 11 Prolift. was generally successful because the patient was 12 12 MR. ISMAIL: Can you restate, please? 13 functioning well? 13 MR. SLATER: There's sometimes these 14 MR. ISMAIL: Objection to form. 14 delays on these videoconferencing. Q (By Mr. Slater) What is your understanding 15 THE WITNESS: No. 15 16 Q (By Mr. Slater) If the patient said that she 16 as to the role that was played by Michelle Cosson and Bernard Jacquetin with Prolift? 17 was not really bothered by a slight bulge and she felt 17 okay, would you recommend surgery to repair a 18 A My understanding is that they were part of a 18 second-degree cystocele? group of surgeons from France who were involved in 19 19 20 developing the product. 20 Α No. 21 0 Do you know what Ethicon's internal criteria 21 Q In forming your opinions in this case, are 22 was for whether or not a Prolift should be utilized on 22 you relying on the articles that Cosson and Jacquetin 23 and their group of physicians in France have published? 23 a woman?

That's part of the literature, yes.

24

24

A No.

Page 34 Page 36 Q Do you feel that the literature that was put information from doctors about their mesh devices? 1 1 out by Jacquetin and Cosson and their group of 2 A Do I know what they do to get information 2 physicians is an important source of information about 3 3 from doctors? I'm not sure what you are asking, what 4 the Prolift? 4 you mean by that question. 5 A It's one of many sources, yes. 5 Q Let me ask you this: Do you know who within 6 Ethicon evaluates the safety of the Prolift? 6 Q Do you know what Bernard Jacquetin and 7 Michelle Cosson were telling Ethicon in 2004 and 2005 7 A I don't. with regard to the Prolift and whether they thought the Q Do you know what Ethicon did to evaluate the 8 8 9 mesh was an appropriate mesh to use in the Prolift? 9 safety of the Prolift on a day-to-day basis once it 10 A No. 10 went on the market? Q Is that of any significance to you? 11 A I don't. 11 12 12 Q Was that of any interest to you? A No. Q Have you seen any literature written by 13 13 Α Jacquetin or Cosson indicating that the use of the 14 14 Q Asked to see any information that Ethicon had Prolift should be limited to certain types of patients? compiled internally about the safety or the efficacy of 15 15 A Yes. I remember reading one of the first 16 the Prolift? 16 descriptions of the product, and they were remarking 17 17 A Could you repeat the question? 18 that they thought it should be used for advanced stage 18 Q To see any information that Ethicon had 19 prolapse. 19 compiled --20 20 Q Do you agree with that? A I'm sorry --21 A No. 21 Q -- internally --22 22 A -- you keep -- the beginning of your question Q Do you know what Ethicon's internal thoughts 23 were with regard to whether the Prolift should be 23 keeps falling out. It may be that my voice doesn't start to pick limited to advanced stage prolapse? 24 Q Page 35 Page 37 A I don't. 1 up until after I say the first few words. Is that 1 2 Q Is that of any significance to you? 2 what's happening? 3 Α 3 A Yes. 4 Do you believe you have access to the same 4 MR. ISMAIL: In part. Sometimes that 5 amount of data and information about the risks and 5 happens and we can follow along. Sometimes 6 benefits of the Prolift as Ethicon does? 6 the first few words just don't come through 7 7 at all, and we just start picking you up in A No. 8 Q You -- would you agree with me that Ethicon 8 mid sentence. It hasn't happened every has access to more information about the risks and 9 9 question, and we've alerted you when it's benefits of the Prolift than you do? 10 10 happened. 11 A I believe that they have access to more 11 MR. SLATER: All right, I'm going to information in regards to the development of the start to say, "My next question." It's going 12 12 13 product, but I've used the product in clinical 13 to be cumbersome, but hopefully that will practice, and so I believe that I have information with help. Because I think what happens is the 14 14 mic picks up the speaker and it takes a regards to that that they might not have. So I do 15 15 16 think that they have more information about its 16 second for it to transfer to the other 17 development, yes. 17 speaker. So I'm just going to start saying, "My next question." Don't -- I don't want 18 Q Did you ever tell Ethicon anything about the 18 outcomes you had with your patients? Did you ever 19 19 you to think I'm like lecturing you. discuss that with anybody from Ethicon? I'm talking 20 THE WITNESS: Okay. 20 about Prolift patients. MR. SLATER: I'm just going to do it so 21 21 22 A I don't remember. Not outside of my 22 the mic will pick up. 23 THE WITNESS: Okay. research. 23 24 Q Do you know what Ethicon does to get 24 (Discussion off the written record.)

	·	1	_
	Page 38		Page 40
1	Q (By Mr. Slater) My next question: Did you	1	A I don't.
2	make any effort to learn what information Ethicon had	2	Q A DDSA is?
3	internally compiled regarding the safety or the	3	THE WITNESS: He keeps dropping off.
4	efficacy of the Prolift?	4	You keep falling off
5	A No.	5	Q (By Mr. Slater) Let me ask you this
6	Q Would that have been of any significance to	6	ma'am, it's okay. It's fine. You don't have to get
7	you?	7	frustrated. It's not it's a technical problem with
8	A No.	8	us talking from a thousand miles away from each other.
9	Q You let me rephrase.	9	A No, I understand. I'm not frustrated.
10	My next question: Do you consider yourself	10	Q If I have to repeat a question
11	to be an expert with regard to the design of the	11	A I'm just informing you.
12	Prolift or a pelvic mesh system like the Prolift?	12	Q it's not a big deal. It's fine.
13	MR. ISMAIL: Objection to form.	13	Okay. My next question is: Do you know what
14	THE WITNESS: I'm not sure what you mean	14	a DDSA is?
15	by that. I think that I'm an expert in the	15	A No.
16	·	16	Q Okay. My next question: Do you know what a
	way that the Prolift works, yes. Q (By Mr. Slater) My next question: Do you	17	clinical expert report is as that is used within
17	, , , , , , , , , , , , , , , , , , , ,	18	Ethicon?
18	have any information at all that you're relying on at		
19	all as an expert in this case about the steps that are	19	A I don't.
20	taken and were actually taken with the design and the	20	Q Okay. You said that you are familiar with
21	development of the Prolift by Ethicon?	21	some biomaterial science that went into the development
22	A Yes, I do.	22	of the mesh through the literature, right?
23	Q What's that?	23	A That's correct.
24	A I understand some of the biomaterial science	24	Q Are you familiar with the literature by
1	Page 39	4	Page 41
1	that went into developing the mesh that's used with the	1	Dr. Klinge? K-L-I-N-G-E. Are you familiar with his
2	Prolift, and that information has been obtained through	2	literature?
3	the literature.	3	A Yes.
4	Q Anything else?	4	Q Do you new question: Do you rely in part
5	A No.	5	on Dr. Klinge's literature about the mesh in the
6	Q My next question: Do you know anything about	6	Prolift in forming your opinions?
7	the steps that Ethicon took as a device manufacturer to	7	A Yes.
8	develop the Prolift, the internal steps that they went	8	Q Do you find Dr. Klinge's literature to be
9	through to get from the point when somebody brought the	9	important in this field?
10	idea to them to the point they put it on the market?	10	A Yes.
11	Do you know anything about that process at all?	11	Q Let me ask you this: Do you know what
12	MR. ISMAIL: Objection to form.	12	Dr. Klinge's opinions are about whether or not the mesh
13	THE WITNESS: Could you be more	13	in the Prolift is safe for transvaginal treatment of
14	specific?	14	prolapse?
15	MR. SLATER: Sure.	15	A Yes.
16	Q (By Mr. Slater) Do you know what design	16	MR. ISMAIL: Objection to form. Go
17	control is?	17	ahead.
18	A I don't.	18	THE WITNESS: Yes.
19	Q Do you know what design requirements matrix	19	Q (By Mr. Slater) Klinge's opinion?
20	is?	20	MR. ISMAIL: Restate, please.
21	A I don't.	21	THE WITNESS: I think it's actually
22	Q FMEA is?	22	MR. SLATER: My next question
23	A You I missed part of that.	23	THE WITNESS: better when his head is
	Q Do you know what an FMEA is?	24	down.
24	Q DO YOU KIIOW WHAT AH HILA IS:		uowii.

Page 42 Page 44 MS. DEMING: Okay. for them? 1 1 2 THE WITNESS: I think it's better when 2 Α No, I don't. 3 3 his head is down. 0 Do you have any idea what they've paid him? 4 Q (By Mr. Slater) Okay. My next question: 4 Α 5 What is your understanding of Dr. Klinge's opinion 5 If I told you that Dr. Lucente testified he's about whether or not the mesh in the Prolift is safe 6 6 been paid 1.7 million dollars, would that surprise you? 7 for treatment of pelvic organ prolapse through the 7 MR. ISMAIL: Objection to form. 8 vagina? 8 THE WITNESS: Would that surprise me? 9 9 A I don't know if he stated specifically that It's a big number. it was or was not safe. My impression is that he feels 10 Q (By Mr. Slater) Looking at this set of 10 that the evidence that he has participated in creating emails, you see that in the first email in the chain, 11 11 which is at the bottom of the page, someone name Bart 12 is not relevant for the mesh that was used in the 12 Prolift. 13 Pattyson from professional education is writing to 13 Dr. Lucente, and he wants to schedule some sort of a 14 Q I'm sorry, let me just ask you a question. 14 When you say "he feels his evidence is not relevant" -dinner in Indianapolis. Do you see that? 15 15 A That's the same email I'm looking at now? A Uh-huh. 16 16 Yes, I think so. 17 Q -- what do you mean by that? 17 18 A When I was reviewing his report, he remarked 18 Q He suggests inviting Douglass Hale to the 19 that the biomaterial science that he helped to generate 19 dinner? 20 is not relevant for the Gynemesh because they were 20 Α Uh-huh, yes. 21 looking at biomaterial science as it related to the 21 Q You did your fellowship with Doug Hale in abdominal -- an abdominal hernia. And he felt that a 22 Indianapolis, right? 22 23 model for vaginal hernias should be the paradigm that 23 That's correct. Α should be used to establish whether or not the mesh was 24 Q Were you aware, when you were training with Page 43 Page 45 1 safe for use with a vaginal hernia. 1 Dr. Hale, that he was a paid Ethicon consultant? Q Okay. So you're not -- let me just 2 2 A I was not. understand. So you're not aware of whether Dr. Klinge 3 Q Did you know that before right now? has offered an opinion directly about whether or not 4 A I did not know that before right now. the mesh in the Prolift is safe for use to treat 5 Q Looking now -- I'm sorry, looking now at the 5 6 Prolift -- prolapse through the Prolift system? 6 second email in the chain, which is actually just 7 A That's correct. 7 towards the top at 3:44 p.m. on September 11, 2007, do Q Based on -- let me just ask you this: Based 8 8 you see Dr. Lucente's email to Bart Pattyson? on Dr. Klinge's work in this field, would that opinion 9 A Yes. 9 10 be significant to you? 10 Q Okay. Dr. Lucente talks about the fact that 11 A It would be something that I would consider, 11 the last time he tried a venue like they're proposing 12 for this meeting, Dr. Hale "flipped, totally got pissed yes. 12 13 MR. SLATER: If we could, can we hand 13 off. It was ugly. He has some issues. We are cool 14 Dr. Lowman Exhibit 17, please. 14 now, but it was insightful as to where his head is at." 15 MR. ISMAIL: Thank you. Do you know what that's -- what that's talking about at 15 16 Q (By Mr. Slater) Okay, Doctor, do you see 16 all? Exhibit 17 that we've handed to you? 17 17 A I don't. 18 A Yes. 18 Q Okay. Now, looking further into that email of September 11 at 3:44 p.m., Dr. Lucente says, 19 Q You see these are some emails in September 19 2007 between some people at Ethicon named Bart Pattyson "Lastly, his senior fellow, Joye Lowman, was a resident 20 20 and Paul Parisi and Dr. Lucente? Do you see that? of mine from Abington. Like Steph, well, needless to 21 21 22 A Yes. 22 say, her loyalty to me was a friction point." Do you 23 Q Have you ever known about the amount of money 23 see that? 24 that Ethicon has paid Dr. Lucente as a paid consultant 24 A I see that.

Page 46 Page 48 Q Do you know what Dr. Lucente is talking about fellowship in Indianapolis, is that accurate? 1 1 2 there? 2 A Well, I mentioned before that he wrote me a 3 3 letter of recommendation. To my knowledge, that's all MR. ISMAIL: Objection to form. 4 4 THE WITNESS: I don't. that he did. 5 Q (By Mr. Slater) Do you consider yourself to 5 Q One other question: Did Dr. Lucente write have a level of loyalty to Dr. Lucente that it caused 6 6 letters of recommendation for you that you were able to 7 friction with Dr. Hale in any way? 7 send to whatever fellowships you were applying to, or 8 A Not that I'm aware of. 8 was it just to this specific one at your request? 9 Q Okay. Where Dr. Lucente says that you had 9 A To whatever fellowships I was applying to. 10 loyalty to him, would you agree with that statement? 10 So was it like a standard letter about you 11 MR. ISMAIL: Objection to form. 11 and then you could give it to whatever fellowship you wanted to as part of your application process? 12 THE WITNESS: I don't know what he means 12 13 by that. I respect Dr. Lucente, but I don't 13 A That's correct. 14 know what he means by loyalty to him. 14 So are you surprised to see Dr. Lucente sort Q (By Mr. Slater) Let me ask you a question: of taking credit for helping you get that fellowship? 15 15 Do you think that's overstating things a little bit? Has Dr. Lucente ever indicated to you that he would 16 16 17 talk to Ethicon about you in emails or in any 17 MR. ISMAIL: Objection to form. 18 conversations? Did you know that you were a subject of 18 THE WITNESS: He wrote the letter of 19 communications with Ethicon about you? 19 recommendation for me. I don't have any 20 A In the last deposition that I participated 20 opinion beyond that. Q (By Mr. Slater) Okay. When you -- when you 21 in, they showed an email where Dr. Lucente had reached 21 out to someone about my employment. That's the only 22 got the fellowship with Dr. Hale, did he tell you 22 23 thing that I'm aware of. 23 anything about whether or not Dr. Lucente's 24 MR. SLATER: If we could, Jon, could we 24 recommendation was of any significance to him in giving Page 47 Page 49 1 show Dr. Lowman Exhibit 18. 1 you that fellowship? 2 2 Q (By Mr. Slater) Okay. Doctor, I've given A No. you Exhibit 18, which is some emails in June of 2009. 3 3 MR. SLATER: Okay, can we give 4 A Uh-huh. 4 Dr. Lowman Exhibit 7, please. 5 Q And in the middle of the page is one from a 5 MR. ISMAIL: Adam, it's been about an 6 guy named Robert Zipfel, a professional education 6 hour, if we can take a break when it's -- if 7 manager at Ethicon, to Vince Lucente. And he's asking 7 this is going to be a short exhibit, we can Dr. Lucente if he's interested in going to Atlanta, 8 8 finish it up. If you're going to be a while, 9 Georgia on a Thursday for a 3 o'clock p.m. Prolift 9 maybe we'll take a break now. 10 surgery with you and other physicians at Northside 10 MR. SLATER: Are we saying we have to Hospital followed by a dinner lecture on Prolift. Do 11 11 take a break every hour? you see that? 12 MR. ISMAIL: I'm not saying that. I'm 12 13 A I see that. 13 just asking if we can have a break. If this 14 Q And do you recall being approached by Ethicon is going to be a long exhibit, we can take it 14 to be involved in performing a Prolift surgery that 15 now. If this will be a short exhibit, we'll 15 16 Ethicon would sponsor and then it would be connected to 16 take it after. a dinner Ethicon would sponsor? 17 17 (Discussion off the written record.) 18 A I don't remember that. 18 Q (By Mr. Slater) Okay, Doctor, I've given you Exhibit 7, which is a set of email -- which actually is 19 Q Okay. And looking up above, you see where 19 Dr. Lucente says that you are his former resident and an email from Scott Finley, who's a division manager in 20 20 you [sic] "helped her secure her fellowship in the sales department at Ethicon, and it's the day after 21 21 Indianapolis." Do you see that? 22 22 the exhibit we just went through. It's now June 16, 23 A I see that. 23 2009. 24 And when he says he helped secure your 24 Α Okay.

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Page 50

Q And you see it's about the Lucente Advanced Prolift Users Program?

A Yes.

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Q And you -- do you know any of the people in the email up above where it says "From" and "To" and the cc's? Do you know any of those people or did you know any of them?

A None of these names ring a bell other than possibly Robert Zipfel, but I don't -- I don't remember why that names looks familiar to me.

Q Okay. Robert Zipfel was in the sales department. Does that ring a bell to you? He was -he was -- he oversaw sales.

A In Indianapolis? I mean, that's the only thing I could think as why that name would look familiar to me.

Q The email says that this guy Scott Finley "attached a target list for each of you to complete and return for me for our Advanced Prolift Program with Dr. Lucente." They're setting -- you can see they're trying to fix the date, and he gives some responsibilities to some of the people on the email for 22 helping to set up this event. Do you see that?

A Yes.

doctors, and they want to go heavy on the competitive folks.

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Page 53

And if you go further down to the proctorship targets, they talk about who they want, "Prolift users, +M users, and any busy competitive doctors who want to learn Prolift. You-all need to discuss this program with every mesh doctor in Atlanta. Seize the moment and let's conquer." Do you see that?

A I do.

Q Let me ask you this: Before right now, are you saying you had no idea that Ethicon was scheduling this proctorship where they were planning to have you operate with Dr. Lucente in an effort to conquer doctors and create new customers for the Prolift?

MR. ISMAIL: Objection.

Q (By Mr. Slater) Are you saying that you knew nothing about this until I showed you this email?

MR. ISMAIL: Objection to form.

THE WITNESS: I don't remember anything like this. I don't know if there was a discussion maybe with Dr. Lucente and some of these reps about coordinating this, and then he was going to reach out to me to get it -to get it together and maybe that part never

Page 51

Q And then he says, "Below is the plan. Thursday (date to be announced), 3 p.m., Prolift proctorship at Northside with Dr. Joye Lowman, and we will need to get credentialing for Dr. Lucente to scrub in. Also need room for eight surgeons to observe." And then at 7 p.m. would be a dinner, Prolift users and competitive doctors. Do you see that?

A I see that.

Q Does this refresh your recollection that you had spoken with Ethicon and agreed to participate in a proctorship for the Prolift in 2009?

A No, I don't remember that.

Q Are you saying that they were scheduling this without even talking to you?

MR. ISMAIL: Objection to form.

THE WITNESS: What I'm saying is I don't remember that.

Q (By Mr. Slater) This -- I'm sorry, this email is 2009. This would have been in the year after you finished your fellowship, correct?

A That's correct.

Q And this talks about further down, "Dinner targets: Need Prolift users, +M users, and competitive users as well." And they want to get at least 30 to 40

1 happened. I don't know. But I don't 2 remember anything like that. 3

Q (By Mr. Slater) Let me ask you this: Was there ever a time where you did a proctorship in Atlanta where you operated and did a Prolift procedure either with or without Dr. Lucente and other doctors observed it through Ethicon? Did that ever happen?

MR. ISMAIL: Objection. Asked and answered.

THE WITNESS: No, I don't remember that ever happening.

Q (By Mr. Slater) Let me ask you this: Do you have any idea why it is that these people at Ethicon thought that they were going to be able to use a procedure performed by you as a Prolift proctorship and to have Dr. Lucente participate in that? Do you have any idea how your name got into this and how they thought you would participate?

MR. ISMAIL: Objection to form.

THE WITNESS: I would have to suspect. I would think that maybe Dr. Lucente thought I'd be able to do something like this, but I don't remember participating in anything like this at all.

Page 54 Page 56 Q (By Mr. Slater) Let me ask you this: Do you 1 Q Okay. So you -- so you joined this medical 1 2 have any recollection of Dr. Lucente ever speaking to 2 practice, and how large is the medical practice, how 3 you about such an event? 3 many doctors? 4 A I don't remember him -- but that -- I mean, 4 A Two. 5 that was, what, a long time ago. I can't add. Six 5 Okay. And is it two doctors currently, or 6 years ago. 6 was it two at the time, or has it always been two? 7 Q Let me ask you this: Have you ever -- I'm 7 A It was just me when I first started there, 8 sorry. Have you ever done any sort of a proctorship or 8 and now it's two. 9 a preceptorship where you have participated in an event 9 Q How did you get that job? What happened to in connection with any mesh device or mesh procedure in 10 get you into that position? 10 connection with a manufacturer where you were training A One of my colleagues and I were talking. 11 11 other doctors or showing other doctors anything about a She's actually from Indianapolis and she -- I was 12 12 procedure? talking about the fact that I wanted to move to Atlanta 13 13 or I was considering moving to Atlanta, and she asked 14 A Outside of fellowship, no. 14 MR. SLATER: All right, if you want to me what I was doing. I told her about my fellowship, 15 15 take a break now, we can do a break now. and she said, "Oh, that sounds like a skillset that we 16 16 could use at Kaiser." And so she passed my CV a long 17 MR. ISMAIL: Great. 17 18 THE VIDEOGRAPHER: We are now going off 18 to the chief of the department at the time. 19 the video record. The time is currently 19 Q Now, when you say "the department," is this 20 11:26 a.m. This is the end of Tape No. 1. 20 at a particular hospital? 21 (Recess taken.) 21 A No. This is at Kaiser. The chief of the 22 THE VIDEOGRAPHER: We are now back on 22 women's services department. 23 the video record with Tape No. 2. The time 23 Tell me -- okay. Tell me what Kaiser is. 24 is currently 11:40 a.m. 24 Α Kaiser is a health management organization Page 55 1 Q (By Mr. Slater) Okay. All right, Doctor, if 1 where physicians are hired to take care of patients who 2 2 you could, let's look back at your report, Exhibit 1. have Kaiser insurance. 3 3 Q Okay. And so it's a group of doctors, and 4 4 then if somebody is part of the Kaiser health insurance Q And if you could, let's go to the second 5 5 company, basically, they go to the doctors that are page. 6 A Okay. 6 hired by that company? 7 Q In the first page over to the second page, 7 That's correct. Α you talk about that you started the urogynecology 8 Okay. And you indicate that there's 250,000 8 9 department at Southeast Permanente Medical Group of 9 members of this -- I guess it's a health insurance 10 Kaiser Permanente Georgia in 2008. Do you see that? 10 company? 11 A Yes. 11 A Right. O What does that mean? 12 Okay. The 250,000 members, they're not all 12 13 A That means that they did not have a 13 potential patients of yours; that includes everybody, urogynecology department before I came and started it. men, women, children, the whole gamut, right? 14 14 Q Let me ask you: When you say they didn't 15 15 Α That's correct. 16 have a department, does that mean they didn't have a 16 0 Okay. How many of the 250,000 members are urogynecologist on staff? actually urogynecology patients? 17 17

15 (Pages 54 to 57)

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A I don't know.

hospital. Which hospital is it?

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hospital?

A Yes.

Okay. Do you have privileges at a particular

MR. GOODALL: Repeat that, Adam.

Q (By Mr. Slater) You have privileges at a

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23 24 A That means they didn't have a department.

They also did not have a urogynecologist on staff, but

Q Well, if they didn't have a urogynecologist

on staff before you joined their staff, they couldn't

they did not have a department either.

have a urogynecology department, right?

A Correct.

Page 58 Page 60 A Northside Hospital, Piedmont Hospital, and MR. SLATER: Sure. 1 1 2 Gwinnett Medical Center, as well as Atlanta Outpatient 2 Q (By Mr. Slater) Have you been a peer 3 Surgery Center. 3 reviewer for any medical journal? Q Okay. Northside Hospital, how many beds is A I don't remember. 4 4 5 that hospital? 5 Q Okay. Let me ask you this: When you were a fellow, did you have teaching responsibilities as part 6 A I don't know. 6 7 Q Okay. Let me ask you this: How many 7 of your fellowship? urogynecologists are on staff at Northside? 8 8 A Yes. 9 A I don't know how many urogynecologists are on 9 Q Other than in your fellowship, have you had staff there. It's a very busy hospital. They deliver 10 10 any teaching appointments? over 5,000 babies a year, but I don't -- I don't know A I have not had any appointments. I have been 11 11 the answer to that question. involved in teaching, yes. 12 12 13 Q When you operate, where do you operate, at 13 Q What do you mean by that? all three or at one in particular of those hospitals? There are Emory residents that rotate through 14 14 A At all three. Piedmont Hospital from the OB/GYN department, and 15 15 Q Okay. Piedmont, how many beds is that sometimes they will observe or assist with surgical 16 16 17 hospital? 17 cases. 18 A I don't know. 18 Q Do you -- let me ask you this: Do you have any sort of a teaching appointment with Emory? 19 Q How many urogynecologists are on staff at 19 20 Piedmont? 20 A No. 21 A None now besides myself. Actually, my 21 Q So they'll observe a procedure you might perform, but you're not actually -- you don't have an partner, my partner and I both have privileges there. 22 22 23 So the only -- the only ones --23 appointment to actually be an instructor of any of 24 Q Who's your --24 these residents --Page 59 Page 61 -- the only ones I'm aware of --1 A I don't get --1 2 Q Go ahead. I'm sorry. 2 Q -- is that accurate? 3 A I don't get paid to teach them, no. 3 A There are two that are on staff there that 4 4 Q And you don't have a particular appointment I'm aware of. where you're some sort of an assistant or associate 5 O Just for the record, who's your partner? 5 6 She is the person that we hired once we 6 professor or anything at a medical school, you don't 7 decided that we needed to expand the department to 7 have those appointments? include another physician besides myself. Are you 8 A That's correct. 8 asking her name? 9 Okay. Let me ask you this: On page 2, you 9 Q Okay. What's -- yes. 10 give some figures, and I want to understand them a 10 11 Dr. Saguan. 11 little bit. Α Q And when was she hired? 12 12 A Okay. 13 2012. 2012, I believe. 13 Q You indicate -- you indicate that you have Q Let me ask you this: Do you currently have performed well over 2700 procedures. Do you see that? 14 14 any teaching appointments? 15 15 A Yes. 16 Α No. 16 Q All right. I want to understand how that breaks down. Just below that, you say you've done 150 17 Do you currently act as a peer reviewer for 17 surgeries using the Prolift. Is that accurate? any medical journal? 18 18 19 A That's accurate, uh-huh, approximately. 19 A No. 20 So is that -- rephrase. Q As a peer reviewer for any medical journal? 20 MR. ISMAIL: Restate, please. The Prolift procedures, the 150 figure, does 21 21 Q (By Mr. Slater) For any medical journal in that include Prolifts that you participated in as a 22 22 23 resident and a fellow? 23 your career? 24 A Yes. 24 MR. ISMAIL: Once again, please.

Page 62 Page 64 Q How many of the Prolifts that you did were 1 1 A I honestly don't remember. 2 you participating in as a resident, how many of the 2 Let me try to refresh your recollection. The 3 3 150? Elevate? 4 4 A I'm sorry, there were none during residency. A No. 5 They were during fellowship. 5 Q The Apogee, the Perigee, the Avaulta? 6 Q Okay. How many of your -- let me rephrase. 6 Α I don't remember --7 How many of the 150 Prolift procedures 7 0 The Pinnacle? 8 occurred during your fellowship? 8 -- specifically. I remember that we did not 9 9 use Elevate or Pinnacle. I don't remember the others A Approximately 80. 10 10 Q And let me ask you: In your fellowship when that we used. you were participating in the approximately 80 Prolift 11 Q Let me ask you this: In either your 11 procedures, would you have been the primary surgeon, or fellowship or your private practice, have you used 12 12 13 would you have been assisting either Dr. Hale or 13 Gynemesh PS flat mesh where you've cut the mesh and somebody else? used it in treating prolapse? 14 14 15 15 A The primary surgeon. Yes, frequently. 16 16 Q Okay. Now, your fellowship ended in 2008, so 0 Would that be an abdominal sacrocolpopexy? 17 the 80 procedures that you're talking about would have 17 Α 18 been from 2005 to 2008? 18 How about through the vagina, have you used 19 A That's correct. 19 Gynemesh PS flat mesh that you've cut and used 20 Q During 2005 to 2008, what other procedures 20 transvaginally to treat prolapse? 21 21 were you performing to treat pelvic organ prolapse Α No. besides the Prolift? 22 Q In your current practice when you do 22 23 A Abdominal sacrocolpopexy, high uterosacral 23 abdominal sacrocolpopexy, what type of mesh do you use? ligament suspension, laparoscopic abdominal 24 Gynemesh. Page 63 Page 65 sacrocolpopexy. 1 Do you use any other types of mesh? 1 2 2 Q Did you perform colporrhaphy during your I have used. I've used Smartmesh. 3 3 fellowship? Q Any other meshes? 4 4 A I'm sure that I did. A I believe I've used IntePro as well. 5 Q Okay. Now, based on the figures you gave, 5 Okay. When you -- when you do an abdominal 6 after your fellowship, beginning in -- when you got out 6 sacrocolpopexy procedure and you cut a portion of 7 in 2008 going forward, that would mean you performed 7 Gynemesh PS flat mesh, what are the dimensions of the approximately 70 Prolifts going forward after that 8 8 mesh that you actually leave in the body? 9 time, correct? 9 A It's usually -- it's approximately 4-by-15 10 10 centimeters. That's correct. 11 Q Can you tell me when you last did a Prolift 11 Q When you cut Gynemesh PS and use it in abdominal sacrocolpopexy, it's in a rectangular shape? 12 procedure? 12 13 A I don't remember exactly. 13 Sort of. It's kind of a rectangular strip. Q Can you tell me approximately when it was, 14 14 Q Once you've cut it and fashioned it, it will 15 what year it was, that you last performed a Prolift? 15 be basically a rectangular strip that you'll implant? 16 A I don't remember. 16 Yeah. Q Let me ask you this: Did you ever use the 17 17 In your career, have you been involved in Prolift+M? 18 treating complications with Prolift from other doctors 18 who had implanted it, where the patient would come to 19 A No. 19 Q Did you ever use a mesh kit other than the 20 you with Prolift complications? 20 21 Prolift to treat prolapse? 21 A I'm sure I have. 22 A Not outside of fellowship, no. 22 Q How many times? 23 Q Okay. In fellowship, what else did you 23 I don't remember. Α 24 utilize, what other mesh kit? 24 Is there anything you remember about any of

Page 66 Page 68 those patients in terms of the complications you 1 A I can speak to the complications that I've 1 2 treated? 2 seen involving mesh in general. I don't remember which 3 patient had Prolift versus which patient had some other 3 A You're asking me about people that were sent to us from outside of our practice, or are you asking 4 type of mesh. I've seen complications from 4 5 in general? 5 transvaginal mesh, and I have treated them. Some of 6 Q What I'm asking you is where a patient came 6 them have been procedures that I did -- that we did in 7 to you, not necessarily sent to you, because some 7 my training program, and I have seen complications in 8 patients self-refer --8 patients that I've treated since training. But I 9 9 A Uh-huh. cannot say which patients had Prolift and which 10 O -- where a patient came to you with 10 patients came from other doctors. I don't know the complications from a Prolift and you didn't implant it. 11 11 answer to that. And I'm asking how many of those, if you recall, and 12 12 Q Let me ask you a question about your what types of complications you saw. 13 practice. Because you're part of the Kaiser Permanente 13 A I don't remember how many that would be, but organization, do you only treat patients that are 14 14 within that network? 15 I'm sure I've seen that. 15 Q Can you estimate the number of times patients 16 A Yes. Well, actually --16 have come to you with complications from a Prolift that 17 17 Q So if a patient --18 was implanted by another doctor? 18 -- let me qualify that. That's not -- that's A I can't estimate that. I don't know. 19 19 not correct. In general, that is correct, but I do 20 O Less than 10? 20 have some patients that pay to see me who don't have 21 A I don't -- I honestly don't know. 21 Kaiser insurance. 22 Q Than a thousand? 22 Q Okay. Where patients have come to you in 23 A It's less than a thousand. 23 your private practice with complications from a mesh 24 Q Than a hundred? kit, were they all Kaiser patients? Page 67 Page 69 1 MR. ISMAIL: Restate, please. 1 Α They were Kaiser patients at that time, yes. 2 Q (By Mr. Slater) Would it be less than a 2 Okay. Let me ask you this: Going back to 3 3 hundred? your report, the 2,700 procedures, is that two hundred 4 MR. ISMAIL: Objection to form. 4 and seven -- rephrase. 5 5 THE WITNESS: It's less than a The 2,700 procedures you listed, are those 6 hundred. 6 2,700 prolapse procedures? 7 MR. ISMAIL: Restate, please. 7 A Prolapse and -- it's not all prolapse, no. 8 O (By Mr. Slater) Would it be less than 20? 8 Q It's prolapse, incontinence, or a 9 MR. ISMAIL: Objection to form. 9 combination? 10 THE WITNESS: I honestly don't know. 10 A Correct. 11 Q (By Mr. Slater) Can you tell me anything 11 Q Of the 2,700 -- well, rephrase. about the complications you saw for those patients who 12 Would that basically be 2,700 pelvic floor 12 came to you with Prolift complications where the 13 13 repair procedures? Prolift was placed by another doctor? 14 A Yes. 14 A It would be conjecture. I can speak 15 15 Okay. Of those 2,700, in looking at your 16 generally. I can't speak about specific patients and 16 report a little further down, you said you've used mesh in over 1200 procedures. Do you see that? 17 who they came from. 17 Q I don't care about specific names or where 18 18 A Yes. they came from. I want to know about the complications 19 19 Q The 1200 would be your fellowship plus your that you've treated for Prolift patients where they 20 private practice? 20 were implanted by another doctor and came to you with 21 21 Α Yes. complications for treatment. 22 22 Q And of that 1200, 150 are Prolift and the 23 A I can't speak to that. 23 rest would either be abdominal sacrocolpopexy or the

handful of other kits you used in your fellowship?

24

Q What you've seen?

Page 70 Page 72 A And midurethral slings. 1 1 A I prefer the retropubic route. 2 Well, this says you've used mesh to treat 2 Q Why? 3 pelvic organ prolapse -- oh, I see what you're saying. 3 A It has a higher success rate. Okay. All right, let me -- I understand now. Of the 4 4 Q Does it have a higher success rate in your 5 2700 procedures, 1200 involved mesh of some sort, 5 hands, or are you saying the literature shows that? 6 whether it was sacrocolpopexy, whether it was a 6 A Both. Prolift, whether it was a midurethral sling --7 7 Q Do you not use the TVT-O because of any 8 Α Right. 8 issues with safety? 9 Q -- correct? 9 Α No. 10 Yes. 10 You're not concerned about injuries in the 11 Q Okay. So 1500 of the procedures would 11 obturator region that are not implicated with the TVT 12 involve no mesh? 12 retropubic? 13 MR. ISMAIL: Objection to form. A That's correct. 13 14 Q What are those procedures? What do those 14 THE WITNESS: That's not the main reason 15 include? 15 why I don't -- why I prefer to use the 16 16 A Those would include pelvic organ prolapse retropubic route, no. repairs that don't involve mesh, for instance, a high 17 Q (By Mr. Slater) I understand it's not the 17 18 uterosacral ligament suspension or a colporrhaphy. 18 main reason, but is that one of your considerations, Q Anything else? one of your reasons for not using the TVT-O? 19 19 20 A Vaginal hysterectomy, colpocleisis. 20 A Is -- can you repeat what the risk was? 21 Q Anything else? 21 Q Sure. Is one of the reasons that you do not 22 A Surgeries to correct complications not 22 use the TVT obturator in your practice because of 23 necessarily just with mesh, but with other procedures. 23 concerns for safety due to the obturator route that's 24 Q In treating incontinence, do you perform the 24 used and the fact that mesh is put into the obturator Page 71 Page 73 Burch procedure? 1 part of the pelvis? 1 2 A I was trained to do that in fellowship. I do 2 I wouldn't characterize it as a concern for 3 not do it now. safety, but pain has been something that's seen more 4 often in a transobturator sling versus a retropubic 4 Q Do you only use midurethral slings to treat 5 incontinence now, or do you use other procedures as 5 slina. 6 well? 6 Q And that is one of your considerations in why 7 A To treat stress incontinence, that's my 7 you use the retropubic? 8 8 procedure of choice, yes. Yes. 9 9 Q Urethral sling or slings do you use? Let me ask you: Have you used any other 10 A I use the TVT. 10 midurethral slings other than the TVT retropubic and 11 Q Which one do you use? 11 TVT obturator? MR. ISMAIL: Restate, please. 12 12 Α Yes. 13 MR. SLATER: Sure. 13 Q What? (By Mr. Slater) Which TVT, since there's a 14 14 The Monarc. Α bunch of different TVT devices, which TVT do you use in 15 15 Q Anything else? 16 your practice? 16 Α A The tension-free vaginal tape, the retropubic 17 17 Q The Monarc, is that something you only used 18 18 in your fellowship? sling. Q You don't use the TVT obturator? A I believe that I used the Monarc once or 19 19 20 20 A Not currently, no. twice after fellowship as well. Q Did you use the TVT obturator? 21 21 O That's an obturator procedure, correct? 22 A In training, yes. 22 Α That's an obturator procedure, yes. Why don't you use the TVT-O since your 23 So you used it just those one to two times 23 Q 24 training? 24 and then decided not to use it because, again, it was

Page 74 Page 76 an obturator procedure? reported with Ms. Hammons, correct? 1 1 2 2 A That's correct. A Right. 3 3 Q Let me ask you a question. On page 3 of your MR. ISMAIL: Objection to form. 4 Q (By Mr. Slater) Have you -- let me ask you 4 report, at the top you say, "I comfortably manage mesh 5 complications, complex female pelvic pain, and 5 this: Have you had patients with mesh erosions where you surgically revised the mesh and then had to do so 6 recurrent prolapse and recurrent or complex urinary 6 7 incontinence." Do you see that? 7 more than once because the mesh erosions recurred? 8 8 Α Yes. A Are you asking about with Prolift or just in 9 9 general? Q With regard to your comfortable management of 10 mesh complications -- I know I asked you this before; I 10 Q Prolift. 11 11 just want to be very clear because you wrote this in A No. your report -- were you speaking about mesh 12 12 Q Are you aware from the literature that that 13 complications from the Prolift? Is that included in 13 does occur with some Prolift patients, that they'll 14 here? 14 have mesh erosion, it will be treated, and then the 15 Α That's included, yes. 15 patient will have a recurrence erosion and sometimes 16 Q Have you personally had patients with the 16 that can happen more than once, more than twice, even, 17 Prolift who have had complications that you had to 17 you know, three, four, five times in some patients? 18 treat that you related to the Prolift? 18 Are you aware of that occurring? A I'm not aware of that occurring with the 19 MR. ISMAIL: Objection to form. 19 20 20 THE WITNESS: I have had patients who Prolift, no. 21 have had Prolift procedures who have had 21 Q In forming your opinions in this case, you 22 complications that we've had to treat, yes. 22 did not assume that there are some patients who get an 23 Q (By Mr. Slater) Can you tell me what 23 erosion with Prolift and it's operated on and then they 24 complications those include? 24 have another erosion and another and that that can Page 75 Page 77 1 A Mostly mesh erosions. 1 happen multiple times, you were not assuming that in 2 2 Q Anything else? forming your opinions, correct? 3 3 A You're talking about treating it surgically, MR. ISMAIL: Objection to form. 4 surgical treatment, or are you including things like 4 THE WITNESS: I'm not assuming, that, 5 physical therapy, estrogen? 5 no. 6 Q Any treatment. 6 MR. SLATER: Okay. 7 A Yes, I mean, there --7 Q (By Mr. Slater) Do you know whether Ethicon 8 knows that that occurs in some patients? 8 O I want to know what the -- well, let me just 9 say -- let me stop. I'm asking you what the 9 A I don't know. 10 complications were. I'm not necessarily asking you 10 Q If Ethicon knows that, is that information 11 what the treatment was. I want to know what the 11 that you would like to have in forming your opinions in complications you had with your Prolift patients where 12 12 this case? 13 vou treated them. 13 MR. ISMAIL: Objection to form. 14 14 A So mesh erosion was the most common. We also THE WITNESS: Not necessarily. saw patients that had scarring or band -- tense sort of 15 15 Q (By Mr. Slater) It wouldn't matter to you in 16 areas of the mesh that was tender to touch. 16 forming your opinions? 17 Q Anything else? 17 A My opinions are based on my clinical 18 A That's mostly what I remember. experience and what I have read in the scientific 18 Q When you talk about tenseness or tense 19 19 literature. So what they know internally is not what I 20 banding that's tender to the touch --20 use to base my opinions on. Q Okay. Let me -- let me walk through this a 21 A Uh-huh. 21 little bit with you. The opinions that you have formed 22 Q -- just to fast-forward a little bit --22 23 23 in this case with regard to the safety and the efficacy A Uh-huh. 24 O -- that's one of the things that Dr. Heit 24 of the Prolift are based on, number one, your clinical

Page 78 Page 80 experience with the Prolift, correct? about this topic, so that's just part of my fund of 1 1 2 2 knowledge"? A Correct. 3 3 Q Number two, your reading of the scientific A It would be the second, more general. MR. SLATER: If we could, Bob [sic], can 4 literature that you've been able to read that's been 4 we hand Dr. Lowman Exhibit 10 and Exhibit 5 published with regard to the Prolift, correct? 5 6 A With regard to the Prolift and other meshes, 6 7 7 (Discussion off the written record.) yes. 8 Relying for your opinions not just on 8 Q (By Mr. Slater) Okay, Doctor, looking at 9 9 literature about the Prolift, but also about other mesh Exhibit 10, there is a set of emails from February of 10 devices and mesh products, correct? 10 2010. And if you look at it, in the middle of the -well, actually, if you go to the second page, there's 11 A Yes. 11 an email that goes from the first page to the second 12 Q Are there any other products or mesh devices 12 that you can list for me that you are relying on 13 page written by Scott Jones, product director at 13 Ethicon. Do you see that? 14 literature about other than the Prolift? 14 15 A I can't list them for you. What I am 15 A Yes. referring to when I say that is the fact that I'm 16 0 Okay. Do you know Scott Jones? 16 relying on meta-analyses and things like the Cochrane 17 A I don't. 17 18 review, which review all transvaginal meshes and not 18 Do you know -- other than what you're reading 19 just the Prolift. 19 here, obviously his title is there, did you have any 20 Q Let me ask you a question: Would you agree 20 idea who he was before I showed you this email? 21 with me that the risk-benefit profile for the Prolift 21 Α No. is not identical to that for other mesh products and 22 22 Okay. This email is written by Scott Jones, Q 23 mesh devices? 23 and you'll see he's talking about needing help to 24 A That's correct. 24 "quantify the number of customers that we have lost to Page 79 1 Q All right, let me ask you this: Other than 1 a competitive procedure focused on apical support. Our 2 your clinical experience and the scientific literature 2 customers continue to tell us that they want to see 3 with regard to the Prolift and those meta-analyses and 3 Prolift+M introduced with an anterior apical product 4 the Cochrane review, is there any other foundation of code." And then he talks about in order to present 4 5 information that you're relying on for your opinions 5 this business case, he needs a bunch of information, 6 about the safety and efficacy of the Prolift? 6 and he talks about needing information about the 7 MR. ISMAIL: Objection to form. 7 doctors that they have lost from the Prolift to other THE WITNESS: We often discuss safety 8 8 procedures. Do you see that? 9 9 and efficacy, what we're seeing in clinical A Let me just read it really quickly. 10 practice, at our conferences and meetings. 10 Q Sure. You can scan through it. I'm just --11 And I rely on that information as well, in 11 that's generally what it's about, but you can take a 12 addition to my conversations with 12 look. 13 colleagues. 13 Α Okay. Q (By Mr. Slater) Anything else? 14 14 Q Okay, so let me ask you just one basic 15 A I think that sums it up. question first. 15 16 Q Okay. Let me ask you this about your 16 Α Uh-huh. When you were performing the Prolift, did you 17 discussions at conferences and conversations with 17 colleagues. 18 have an understanding that in addition to treating a 18 cystocele, that it should also provide some benefit to 19 A Uh-huh. 19 20 an apical prolapse or apical weakness as well? 20 Are there any in particular that you can tell me about right now and say, "This is a discussion that A What type of Prolift are you referring to? 21 21

Let's talk about an anterior Prolift to begin

No, the anterior Prolift doesn't provide

22

23

24

Q

Α

with.

I had and this is information that I'm specifically

just say, "I know I've spoken to people in general

relying on," or is it more general than that where you

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23

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Page 82 Page 84 apical support. 1 1 incorrect. 2 Q Which Prolift provides apical support? 2 MR. SLATER: Okay. 3 A The posterior Prolift. 3 Q (By Mr. Slater) Let me ask you this: The 4 Q Would the total also provide apical support? 4 Prolift stopped being marketed as of September 1, 2012. 5 A Yes. 5 Uh-huh. 6 Q If you turn to the front page of this email, 6 Q Are you aware of that, that that was when 7 in the middle of the page, there's an email from Robert 7 they stopped marketing it? Zipfel to several people. And again I'm just asking, 8 8 A I remembered that it was 2012 or I had a 9 do you know Robert Zipfel or have any involvement --9 gestalt -you ever have any involvement with him or know who he 10 10 O Are you saying that you were -- okay, I'm 11 is? sorry. So you -- after your fellowship, beginning in 11 2008 through September of 2012, which is four years, 12 A I believe that I have. I recognize the name, 12 13 but I don't remember him specifically. 13 approximately, you did 70 Prolifts, according to the Q Do you have any recollection of what figures we went through earlier, correct? 14 14 connection you ever had with him? 15 15 A Yes, approximately. A I don't remember. 16 Q Approximately how many prolapse repair 16 17 Q Robert Zipfel writes, "Last week at the 17 procedures did you perform during those four years 18 summit, it was clear that our physicians want anterior 18 total? Can you estimate that number? apical support modification to Prolift." Do you see 19 19 A How many prolapse procedures did I do during that? 20 20 the four years total? I don't know. 21 A Yes. 21 Q Did there come a time when you were doing --22 22 Okay. And then they had asked for a list. well, rephrase. 23 And at the top, there's an email and it says, "Attached 23 In your practice after fellowship, was there is the list." And Exhibit 11 is a portion of the 24 a point where you were doing more Prolifts and then it Page 83 Page 85 list, and if you look at the -- about halfway down, 1 tapered off? 1 2 2 you're listed and that your product conversion was to MR. ISMAIL: Objection to form. sacrocolpopexy. Do you see that? THE WITNESS: I don't remember. I 3 3 4 4 A I see -believe so. 5 5 MR. ISMAIL: Objection to form. (By Mr. Slater) And why was that? 6 THE WITNESS: I see that. 6 Α Because of the FDA Public Health 7 Q (By Mr. Slater) Okay. Is it accurate that 7 Notification. you stopped using the Prolift because of concern over 8 8 0 Which one? 9 9 the lack of apical support with the Prolift? Α 2011. 10 10 Why did that impact your volume of Prolift Α No. Q 11 MR. ISMAIL: Objection to form. 11 procedures? MR. GOODALL: Adam, you're going to have A Patients became acutely aware that there were 12 12 13 to repeat that. 13 reports of complications because of all the 14 advertisements on TV. 14 Q (By Mr. Slater) Next question: Doctor, why Q When you say "advertisements on TV," are you 15 did you stop using the Prolift? 15 16 A I stopped using the prolapse -- Prolift when 16 talking about advertisements by law firms? A I'm assuming that's who they're by, yes. 17 it was no longer marketed, from what I remember. 17 Q Okay. Let me ask you this: This document 18 Q You said that your use tapered off after the 18 Public Health Notification in 2011. Was there 19 says that as of February of 2010, the -- they had data 19 that you had switched from the Prolift to 20 something about that Public Health Notification that 20 caused you to taper off your use of the Prolift? 21 sacrocolpopexy. Are you saying that information is 21 22 untrue? 22 Α No. 23 MR. ISMAIL: Objection to form. 23 Did you ever consider using the Prolift+M? 24 THE WITNESS: I'm saying that that's 24 Was that ever presented to you?

Page 86 Page 88 A I -- I did consider it, yes. Q In determining what type of mesh you use in 1 1 2 Q You said you never used it. Why? 2 your clinical practice, is the pore size of the mesh 3 A It takes a lot to get me to change from what 3 something you consider? I'm doing. If I'm satisfied with what I'm currently 4 4 Yes. Α 5 doing, then I don't usually switch unless there's some 5 Q Why is that, why do you consider the pore 6 compelling reason. 6 size? 7 7 Q Did Ethicon provide you information about the Α Because the pore size is important to how the 8 Prolift+M? 8 mesh performs. 9 9 Not that I remember. Q Tell me about that. Why is that -- why is Α 10 For example, did a sales representative 10 the pore size important to how the mesh performs? provide you information or invite you to any sort of a A It helps to determine how well the mesh is 11 11 meeting or did you see any presentations at a 12 incorporated into the body. It also helps to determine 12 conference about it that Ethicon sponsored, anything the risk of infection with the mesh, and it helps to 13 13 14 like that? 14 determine the mesh -- its pliability. 15 A I may have seen something at a conference. I 15 Q Do you know the pore size of the mesh in the Prolift? don't remember specifically. 16 16 Q You're -- are you saying a sales -- did a 17 A I do. 17 18 sales representative provide you information about the 18 Q What is it? Prolift+M? 19 A 2.4 millimeters. 19 20 20 A Not that I remember, no. Q Is that uniform across the entire Prolift, 21 Q Anybody from Ethicon ever tell you that they 21 all the pores are 2.4? 22 internally believed that the Prolift+M could have 22 A I don't know. 23 safety advantages for patients because of the fact that 23 Do you know what happens to the Prolift mesh it was a larger pore, lighter weight mesh than the 24 when it's placed under strain and when tension is Page 87 Page 89 Prolift? 1 placed on it? 1 2 2 MR. ISMAIL: Objection to form. MR. ISMAIL: Objection to form. 3 THE WITNESS: Can you repeat the 3 Q (By Mr. Slater) Do you know what happens to 4 4 the pores then? question? 5 5 MR. SLATER: Sure. A I don't. 6 Q (By Mr. Slater) Did anybody from Ethicon 6 Q Do you know what Ethicon's internal knowledge 7 ever communicate to you that Ethicon thought that there 7 is about what happens to the pore sizes of the Prolift were potential safety benefits to the Prolift+M because when it's placed under tension in actual use in the 8 8 9 9 body? it had a larger pore, lighter weight mesh than the 10 Prolift? 10 Α 11 MR. ISMAIL: Objection to form. 11 You -- we had talked about the literature by Q Dr. Klinge a little earlier. Have you read his 12 THE WITNESS: No. 12 13 Q (By Mr. Slater) Do you know anything about 13 literature where he has discussed the importance of the the mesh used in the Prolift+M, for example, what type mesh maintaining at least a thousand microns of pore 14 14 15 size under strain? 15 of mesh it is? 16 A I know that it's a partially absorbable mesh. 16 Α No. Have you read the literature discussing the 17 Q And how do you know that? 17 18 A Through the literature and through 18 importance of having at least a thousand microns of pore size in all directions when the -- when the mesh 19 conferences. 19 20 is incorporated into the body? 20 Q Do you know anything else about the mesh other than that it's a partially absorbable mesh? A I'm familiar with the literature that 21 21 22 A That it's ultra lightweight as well. 22 states that the pore size needs to be greater than 23 Do you know anything about the pore sizes? 1 millimeter. I don't remember it saying anything Q 23 24 No. 24 about being under strain. Α

Page 90 Page 92 Q You do know -- well, rephrase. 1 THE WITNESS: I don't remember. 1 2 And certainly one of the things that you rely 2 (By Mr. Slater) What did the sales rep from 3 3 Ethicon tell you about why Ethicon had stopped selling on for your opinions is that literature that discusses 4 the Prolift? 4 and establishes the need for the pore sizes to be at 5 least 1 millimeter, correct? 5 A He just sort of shook his head and -- he 6 That's correct. 6 didn't give me any specifics. I don't know. I don't Α 7 But you're not familiar with literature 7 remember anything in -- anything specifically. Q Q So let me understand. You sought out the 8 or documents that talk about the need for it to be 8 9 sales rep from Ethicon at your hospital, Northside? 9 1 millimeter even when it's under tension or strain when it's actually implanted in the body? 10 Α Uh-huh. 10 MR. ISMAIL: Objection to form. Q You asked him, "Why is Ethicon stopping 11 11 selling the Prolift?" 12 THE WITNESS: Not in the literature, 12 13 13 Α Uh-huh. no. 14 He shook his head and gave you no information 14 Q (By Mr. Slater) Do you know anything about 0 at all and that was the end of it? 15 the relationship between the need for a 1-millimeter 15 pore size and the propensity of the mesh to develop 16 16 scar plating or bridging fibrosis? 17 Did you make another effort after that to get 17 Q 18 A Yes. 18 that information from somebody else who could actually answer your question? 19 Q And is it your understanding that it's 19 20 important that the pore sizes be at least 1 millimeter 20 A No, because if it's no longer being marketed, 21 in order to reduce the risk of scar plating? 21 it's -- I mean, it's no longer being marketed. I was 22 MR. ISMAIL: Objection to form. 22 just curious. And if he couldn't answer it, who else 23 THE WITNESS: Yes. 23 would I ask? 24 Q (By Mr. Slater) Do you know why the Prolift 24 Q You got hired to be an expert for Ethicon in Page 91 was removed from the market? a Prolift case. As part of your work as an expert, did 1 1 2 MR. ISMAIL: Objection to form. 2 you seek to find out why Ethicon stopped selling the 3 3 THE WITNESS: I don't. Prolift? 4 Q (By Mr. Slater) And just -- there was an 4 A No. 5 objection to the form, so I'm just going to ask it 5 Q It didn't matter to you? 6 differently. Do you know why the Prolift -- rephrase. 6 Α 7 Do you know why Ethicon stopped marketing the 7 Once you got retained as an expert, did you ask anybody, "Why did Ethicon stop selling the 8 Prolift? 8 9 9 Prolift"? A No. 10 Q Did you ever try to find that information 10 A No. 11 out? 11 Q As we sit here right now, are you curious why Ethicon stopped selling the Prolift? 12 I did. 12 Α 13 Q How did you try to find that out? What did 13 A I don't think that has any relevance to my 14 you do? 14 professional opinion about the facts of this case. They decided to stop marketing it. Beyond that, you 15 A I found the rep for Ethicon at Northside and 15 16 asked why they were no longer marketing the Prolift. 16 know, I don't have any further opinion about it. Q Where were you trained on the Prolift, to do 17 Q Who was that? 17 18 A I don't remember his name. 18 the Prolift procedure? Q Okay. And when did this conversation take 19 19 A At Indiana University. 20 20 Q During your fellowship? place? 21 A I don't remember. 21 Α 22 O Was it before the Prolift went off the 22 When you were a resident, did you observe Q 23 market, or was it after it went off the market? 23 Prolift procedures? 24 MR. ISMAIL: Objection to form. 24 A I don't remember. I don't believe so. I

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believe that my first visual evaluation of the product 1 2 was in fellowship. I do remember a lecture.

- O When you were in your residency -- I'm sorry. When you were in your residency, did you know of the existence of the Prolift?
 - A Yes.

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- 7 Q How did you know about the Prolift in your 8 residency?
- 9 A Dr. Lucente talked -- spoke about it in one 10 of his lectures.
 - Q What did he say?
- 12 A I don't remember.
- 13 Q Did Dr. Lucente talk about his personal data or the outcomes of his patients when he spoke about the 14 15 Prolift?
- A No. This was -- that would have been beyond 16 17 the scope of a resident lecture.
 - Q You went to your fellowship and then how were you exposed to the Prolift in your fellowship?
 - A What do you mean by that?
- 21 Q I'm trying to ask as broadly as I can. What 22 was the first involvement, how did you become involved 23 with the Prolift during your fellowship?
 - A Well, during fellowship, we performed

1 THE WITNESS: I don't remember.

MR. SLATER: Okay.

3 Q (By Mr. Slater) Is it fair to say that you 4 would not be able to tell me anything that you might 5 have seen or learned during professional education on 6 the Prolift because you can't remember whether or not 7 you attended such an event; is that fair?

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A No, that's not fair. I can't remember when I attended professional education about the Prolift. I'm sure that I have attended some professional education about the Prolift. And I'm familiar with the information that is usually described in those situations. But I can't say when I did that or whether or not that was a part of my fellowship.

- Q Well, I'm not asking if it was part of your fellowship, I'm actually distinguishing, but let me ask you the question more clearly. As you sit here now --
- A Uh-huh.
- 19 Q -- do you recall attending a professional 20 education event regarding the Prolift?

A I don't remember a specific professional event. What I can say is I've attended a lot of professional events, and I'm sure that the Prolift, 24 if -- that the Prolift may have been one of them.

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procedures usually at the direction of our program directors. So I'm assuming that one of the program directors felt that that procedure was indicated in a patient that we were going to operate on together and that's what we decided to do.

- Q Were you trained on how to perform the Prolift procedure in your fellowship before you took part in those procedures?
 - A Yes.
 - Q Who trained you?
- A I don't remember. It would have been one of my program directors, either Dr. Hale or Dr. Woodman.
- Q Did you ever attend a professional education presentation sponsored by Ethicon regarding the Prolift procedure?
 - A I may have. I don't remember specifically.
- Q Well, I need to -- I need to know -- you have to understand, this is the time I get to ask you questions and learn things.
 - Α Yes.
- Q So I need you to think real hard for me. Did you, yes or no, attend a professional education event regarding the Prolift sponsored and run by Ethicon? MR. ISMAIL: Objection to form.

Q You don't know if you attended a Prolift professional education event, you think you may have

2 3 but you don't know; is that true?

- A That's correct.
- Q Okay. As you sit here now, am I correct that you don't recall actually attending a professional education event with regard to the Prolift and at that event actually seeing a particular lecture, a particular PowerPoint, being given particular materials, you don't remember that because you don't
- 10 11 remember whether you attended such as event; is that 12 true?
- 13 That's true.
- 14 Q You've attended professional education events 15 for various procedures, correct?
 - A Correct.
- Q Okay. Did you attend a professional education event with regard to the TVT or the TVT-O? 18
 - A I don't remember.
- 20 Q Is there any particular mesh device that you 21 do remember actually attending a professional education 22 event for?
- 23 A When you say "professional education event," 24 what do you mean?

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Q Where a mesh manufacturer has one of their preceptors, one of their consulting doctors actually teach doctors through a lecture and then potentially even by demonstrating the surgery after the lecture, "This is this mesh device, this is how it works, this is the data, these are things you need to know," and demonstrating it to teach doctors how to do the procedure.

A Okay. Then I would not have attended something like that in fellowship.

Q Okay. How about after your fellowship?

No. I already knew how to do the procedure.

So the training you got on the Prolift was in the context of your fellowship from the fellowship directors who just taught you in the operating room, basically, "This is what the Prolift is and this is how you do it," is that correct?

A That's correct.

Q Did your fellowship directors show you videos about the Prolift as part of your training?

Not that I remember.

O Did your fellowship directors show you

PowerPoints or literature from Ethicon about the

24 Prolift?

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MS. DEMING: Let him finish his question.

THE WITNESS: Oh, sorry.

Q (By Mr. Slater) Do you -- that's fine.

Do you recall that happening with the Prolift where your fellowship director said, "Hey, you know, you should look at this article about the Prolift, it has important information, you should read this"? Is there any particular article you can point to?

A Not that I remember.

Q Okay. In your report, you focused on certain medical literature. Is that literature that you focused on the literature you just -- you personally think is most important with regard to the Prolift in forming your opinions?

Could you ask that question again?

17 Sure. In your report, you actually discuss 18 certain medical literature, certain studies and certain 19 articles.

A Yes.

0 You pick certain ones and actually talk about 22 them in your report, correct?

A Correct.

Q All right. First of all, were those the

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Not that I remember.

Did your fellowship directors, when they were training you on the Prolift, give you specific medical literature and say, "You should look at this literature to help learn about the Prolift"?

A They didn't often give us literature. I mean, that was something that we did often, reviewing the literature, but it wasn't often given to us by our program directors.

Q Did the fellowship directors suggest that you read any particular literature to help you to learn how to perform the Prolift or to -- or how to determine who to use it with?

A It was customary for us to be reviewing literature. I don't remember either of them giving us anything specific.

Q When you say -- and when you say "giving," not just handing it to you, but suggesting, "Hey, you should read this article, this is a good article about the Prolift, you'll learn some valuable information," that -- you don't recall --

A Oh, we had those types --

Q -- that happening either?

A -- of discussions all the time, sure.

studies and the articles you felt were most important and most significant to you in forming your opinions

3 about the Prolift? 4

A They were articles that I thought helped to elucidate the ideas that I was trying to describe in the report, yes.

Q Okay. And the reason I'm asking is because obviously there's a lot of literature out there and there's a lot of literature on your list that's attached to your report.

A Right.

But you obviously made decisions on what to actually discuss in your report, correct?

A Correct.

And I'm trying just to understand your thought process. The articles that you actually and the studies that you actually discuss in the report are those that you -- are those the ones you felt were most important to you in forming your opinions?

MR. ISMAIL: Objection to form.

THE WITNESS: It doesn't mean that some of the other articles may not have been important. It just means that those are the ones that illustrate the points that I was

Page 102 Page 104 trying to make in the report. make you do that. I'm actually trying to short-cut a 1 1 2 Q (By Mr. Slater) The list of medical 2 little with how I'm asking the question, but my feeling 3 literature on your report, did you compile that 3 would be that you would know which articles are most important to you or which studies are most important to 4 vourself? 4 5 A Not completely, no. 5 you in forming your opinions. So that's what I'm 6 Q Have you read all the articles that are 6 trying to understand, so that when I see you testify at 7 listed in the appendix to your report? trial, I can anticipate what you'll probably focus on 7 8 A At some point, yes. 8 when you testify. 9 9 Q And this is -- this is what I'm trying to get A The only hesitation I have with doing that is at with my question before, since there's obviously a 10 10 that there's a lot that I've read in my career. And lots of articles listed there and I was not -- I was there might be something that comes to mind as we 11 11 progress through this that I realize, oh, this -- in 12 hoping not to walk through every single one of them 12 13 with you. 13 this article, they said something very important. So I don't want to exclude things that might have something 14 A Yeah. 14 of importance in them. I can try to go through this 15 So what I was trying to get at is, I know 15 list if you'd like. you've listed a lot of articles, but I just want to 16 16 understand, those that you describe and discuss in the 17 Q What I want to understand is this: As you 17 18 report itself, are those the ones that you felt were 18 sit here now, other than what you've discussed the most important ones to you in illustrating and 19 specifically in the report, are there any other 19 20 forming your opinions? 20 articles that jump out at you and you say, "This one is MR. ISMAIL: Objection. Asked and clearly important to me also; I didn't discuss it, but 21 21 22 22 it's significant"? answered. 23 THE WITNESS: What I'm trying to explain 23 A I'd have to go through this and try to 24 is that there may be other articles that are 24 remember and figure it out. I don't think I can answer Page 103 Page 105 important that I didn't cite specifically. that question effectively. 1 1 2 The articles that I cited specifically 2 MR. ISMAIL: And, Adam, just so you 3 usually are relevant to either the numbers 3 know --4 that I used specifically or to the specific 4 Q (By Mr. Slater) Any that jump out at you? 5 sentence that was -- that I typed up before I 5 MR. ISMAIL: Sorry, just to interpose, 6 cited those articles. 6 there's a -- there's a supplemental list that 7 Q (By Mr. Slater) This list of medical 7 we've tendered as well, but I know you're --8 literature in the appendix to your report, the reliance 8 MR. SLATER: I don't know what you're 9 list of medical literature, am I correct that you don't 9 talking about with a supplemental list. I weigh all these articles equally, you don't say they 10 10 have this report. 11 all have the same importance to your opinion? MR. ISMAIL: I understand what you have 11 A That's -- yeah, that's correct. 12 12 and that's why I interposed it, so you were 13 So if my starting point -- if I want to 13 aware. figure out which articles were most important to you, 14 14 MR. SLATER: Was it sent to me? certainly those you discussed in your report would be MR. ISMAIL: I have no idea if it was 15 15 16 at the top of the list, correct? 16 sent to you. I'm telling you it's here. 17 A Correct. 17 MS. DEMING: It was sent yesterday. Q Are there any other particular articles, and MR. ISMAIL: It was -- we believe it was 18 18 you can look at the list, where you'd say, "These 19 19 sent yesterday. It's here. additional studies are important to me also, and I put MR. SLATER: Well, you understand I'm 20 20 21 them also at the top of the list in forming my 21 the lawyer that was going to take the 22 opinions"? 22 deposition. Did anybody actually email it to

me and say, "Hey, here's a supplemental list

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of literature"?

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You want me to go through them all?

Q Well, I'm not -- I'm actually not trying to

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Page 108
                                                   Page 106
           MR. ISMAIL: I just told I don't know.
                                                                 there any others on this list that you can tell me,
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           MR. SLATER: Do you think somebody could
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                                                                 "Yes, those are important to me also in forming my
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        do that for me now so during a break I could
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                                                                 opinions; I put them right up there with the ones that
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                                                                 are discussed in the report"?
        take a look at it?
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           MR. ISMAIL: I'm sure that can be done.
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                                                                    A Okay.
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           MS. DEMING: I'll be glad to.
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                                                                        MR. ISMAIL: Objection to form.
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           (Discussion off the written record.)
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                                                                    Q (By Mr. Slater) There might be some; there
        Q (By Mr. Slater) Doctor, as you sit here
                                                                 may not be any.
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                                                                    A Okay.
    now --
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                                                                        MR. ISMAIL: Objection to form.
        A Yes.
                                                                        THE WITNESS: The first article I would
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        Q -- looking at the reliance list of medical
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    literature that was attached to your report --
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                                                            12
                                                                    say is important.
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                                                            13
                                                                    Q (By Mr. Slater) That's the Abed systematic
        A Yes.
        Q -- are there any of those articles that jump
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                                                            14
                                                                 review?
    out at you and you say, "I know that this is important
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                                                            15
                                                                    A Yes. The -- they're not numbered, so this is
    to me also in addition to what I discussed in my
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                                                                going to be --
    report," as you sit here now?
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                                                                        THE WITNESS: Could I have a pen,
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        A I'd have to go through them and look. If you
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                                                                    please.
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    want me to do that, I can.
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                                                                    Q (By Mr. Slater) Alphabetical order, so you
        Q Sure, take a look.
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                                                                 can just tell me the last name of the author.
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           THE WITNESS: Does anyone...
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                                                                        Okay. The first Altman study.
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           MR. SLATER: It's attached to your
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                                                                        That's in your report, you discuss that in
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                                                                the report, right?
        report.
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           THE WITNESS: Yep, I see it.
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                                                                    A Yes, I did.
                                                   Page 107
                                                                                                               Page 109
           MS. DEMING: And then there were the
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                                                                    Q I don't need you to list those that are
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                                                                 discussed in the report. I just want to know, in
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        additional articles that we included in
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                                                                 addition to those you actually discussed in the report,
        the --
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                                                                which ones are also very important to you.
           MR. SLATER: I don't want the additional
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        articles. Ma'am, I don't know why you're
                                                             5
                                                                    A Okay. The second Altman study. The last
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        talking about the additional articles. That
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                                                                Altman study. The Amid study. The Araco study. The
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        will be a separate part of this deposition.
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                                                                Aungst study. The optimal study.
                                                                    Q Which one?
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        I'll take my deposition, okay? I asked
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        Dr. Lowman to look at that reliance list that
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                                                                        The optimal trial.
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        was attached to the report that was served,
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                                                                    O Who's the first listed author?
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        and that's what we're talking about right
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                                                                    A Dr. Barber.
                                                            12
                                                                    Q Got it.
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        now.
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           THE WITNESS: So you'd like me to go
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                                                                    Α
                                                                        The third Barber article.
        through and speak to which articles I think
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                                                                       Success?
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        would be of importance?
                                                            15
                                                                    A Yes, "Defining Success." The Bartley
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        Q (By Mr. Slater) Ma'am -- Doctor, I think
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                                                                article. The Bartuzi article. The Benbouzid article.
    I've asked this question six times. In your report,
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                                                            17
                                                                Dr. Benson's article. Dr. Bhatia's abstract. The
    you discussed certain articles --
                                                                Caquant article. The Carey article. I think I cited
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                                                            18
                                                                that. The Climent article. The Cosson article.
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        A Yes.
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        Q -- which you have acknowledged to me would
                                                                    O Which one?
    certainly be very important to you at the top of the
                                                                        The first one that's listed.
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    list. All I want to know is, you've got pages and
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                                                            22
                                                                    Q
                                                                        The 687 patients?
    pages of lists of articles, some of which you didn't
                                                            23
                                                                        Yes.
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                                                                    Α
24
    even put on this list. So I just want to know, are
                                                            24
                                                                    Q
                                                                        The abstract?
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	Page 110		Page 112
1	A Yes.	1	important.
2	Q Got it.	2	MR. SLATER: Oh, you did.
3	A I believe I cited the Da Silveira article.	3	THE WITNESS: I thought that I did.
4	The I can't pronounce his last name, the	4	THE WITNESS: Murphy. The 2008 article.
5	second-to-the-last one listed on this page.	5	The Nguyen article. The Nygaard article I
6	Q D-A-M-O-I-S-E-A-U-X?	6	believe I cited. Both of those would be
7	A That's correct.	7	important.
8	Q Okay.	8	MR. SLATER: Both of the Nygaard
9	A De Landsheere. I cited that article. The	9	articles?
10	Demirci article, both of those and both of the	10	THE WITNESS: Uh-huh.
11	De Landsheeres. The Dietz article I believe I cited.	11	MR. SLATER: Okay.
12	The El Haddad article. The last Fatton article. The	12	THE WITNESS: Okui, Olsen, Pandit,
13	Feiner articles. The Francis article. The Glatt	13	Patel, both of those
14	article. The Gupta article. The Gutman article. I	14	MR. SLATER: Which one?
15	cited Halaska. The article by Handa. The Heinonen	15	THE WITNESS: Both of them. Perez and
16	articles. The Iglesia article. The Ignjatovic	16	Perschler. I'm sorry, not Perschler, I
17	article.	17	thought that was one article. Popov,
18	Q Which one?	18	Salimova, Sand, Sanses, Sato. Silva I
19	A The second one. Jacquetin.	19	believe I cited. Skala. Sokol I believe I
20	Q Which?	20	cited. Su. Both of those. Subak. Sung.
21	A All of them. The Kahn article I believe I	21	Q (By Mr. Slater) You said Sun or Sung?
22	cited. The Karram article. The Komesu article. The	22	A Sung, S-U-N-G.
23	Kozal articles.	23	Q Okay. Got it.
24	Q Doctor, you can keep looking and indicating	24	A Svabik. Toglia I believe I cited.
	Q Doctor, you can keep looking and indicating	27	A Svabik. Togila i believe i cited.
	Page 111		Page 113
1	them on your you know, for yourself. They're going	1	Vaiyapuri, two-year outcomes. Vaiyapuri, three-year
2	to change the tape, but hopefully they can do that	2	outcomes. The Valentim-Lourenco article. Velemir.
3	quickly and we can continue.	3	Wang, the first the second study. Weber I believe I
4	A Okay.	4	cited. The last Weber article. Whiteside. All of the
5	THE VIDEOGRAPHER: We are now going off	5	Withagen articles. Wong and Dietz, Wong's ICS
6	the video record. The time is currently	6	abstract, Wu, Yakasai.
7	12:59 p.m. This is the end of Tape No. 2.	7	Q There's two Wus.
8	(Recess taken.)	8	A Oh, I'm sorry. The second Wu.
9	THE VIDEOGRAPHER: We are now back on	9	Q Okay.
10	the video record with Tape No. 3. The time	10	A And Yazdany and Yesil.
11	is currently 1:04 p.m.	11	Q All right.
12	THE WITNESS: So I'm looking at the page	12	MR. SLATER: Now, you guys mentioned
13	with Krasnopolsky or polsky (pronunciation)	13	lunch. Do you want to break for lunch now
14		14	and then come back soon?
15	at the top. MR_SLATER: Right	15	MR. ISMAIL: Sure.
	MR. SLATER: Right.		
16	THE WITNESS: Those first three articles	16	MR. SLATER: Or do you want to keep
17	I would think might be important. The Lane	17	going? I'll do whatever you want.
18	article, the Lensen article, Liang, Long,	18	MR. ISMAIL: No, let's take a break.
19	Long, Lowder, Lucente's last two articles,	19	(Discussion off the written record.)
20	Lykke, Maher, and I believe I cited one of	20	THE VIDEOGRAPHER: We are now going off
21	those, but all of the Maher articles. McEvoy	21	the video record. The time is currently
22	on the next page, McLennan, Milani, Miller.	22	1:13 p.m.
23	I cited the Murphy "Time to Rethink" article,	23	(Lunch recess taken.)
24	I believe. If I didn't, that would be	24	THE VIDEOGRAPHER: We are now back on

Page 114 Page 116 1 -- are you going to tell me that you --1 the video record. The time is currently 2 2 I've watched an anatomy video in the past. I 1:56 p.m. 3 3 don't know which one is -- there's several here, so I'm Q (By Mr. Slater) Okay, Dr. Lowman --4 4 not sure which of those anatomy videos I've actually Α Yes. 5 -- I'm looking at your report, and you also 5 watched or not watched. I have not watched them all. 6 have a list after the list of literature of what you 6 Q Is it possible that the anatomy video that 7 called production materials at the end. 7 you've seen in the past is not one of these? 8 A I don't know if that's possible or not. I'm 8 Α Okay, let me get to that. 9 9 assuming that this is exhaustive. Q Sure. 10 This is after the reliance list you're 10 Q When you say you've seen an anatomy video --Α 11 talking about? 11 Α Uh-huh. 12 After the list of literature --12 -- are you able to tell me -- you're not able 0 Q 13 to tell me which of these you have may have seen? 13 Α Yes. 14 Q -- the next thing, you have a list of 14 15 production materials. 15 O Is that correct? Yes. 16 A That's correct. 16 17 Okay. What I'd like to do is ask you, first 17 Q Is the anatomy video that you saw, regardless Q 18 of all, is this a list of materials that you compiled 18 of whether you can tell me which one it is --A Uh-huh. yourself? 19 19 20 20 A Not completely myself, no. -- of any significance to you in your Have you actually looked at everything on 21 opinions in this case? 21 this list of production materials, these three pages? 22 A No. 22 23 I've looked at most of this at some point, 23 If we go to the last -- the third page of the 24 yes. 24 production materials, there's a series of Prolift Page 115 Page 117 1 Q Well, before you became an expert in this 1 professional education videos. Are those of 2 case, had you looked at -- other than -- well, 2 significance to you in forming your opinions in this 3 3 rephrase. case? 4 4 Before you were retained as an expert, had No. Α 5 you looked at these materials? 5 Q Did you even watch those in connection with your work in this case? 6 A No. I may have looked at an anatomy video, 6 7 but certainly not this expansive materials, no. 7 Α No. Q So basically you were just provided a bunch 8 8 Q Do you even know if you've ever seen any of 9 of -- talking -- you just mentioned videos, so I'll 9 them? just talk about the videos. You were just given a 10 10 A I don't know if I've seen these specifically. bunch of videos that were from Ethicon, and did you 11 11 I have seen professional education videos during my actually watch them? 12 12 career. A I've watched anatomy videos over the course 13 13 Q You just don't know if it's those? of my career. I haven't watched all of these videos in 14 I don't know if it's those. 14 the past three months, no. 15 O If we go to the first page of the production 15 16 Q Have you watched any -- let's rephrase. 16 materials, there's a list of -- at the beginning a Talking on the first page, there's a series series of materials, and I'll just go through them real 17 17 of anatomy videos. quick. 18 18 19 19 A Yes. Α Okay. 20 20 Q Have you watched any of those, those specific There's one that just has some Bates numbers anatomy videos, have you watched them? on it. Do you know what that is? 21 21 A No, not recently. 22 22 A I don't know what a Bates number is. Q When you say "not recently" --23 23 It says ETH.MESH.020 --Q 24 Uh-huh. I've watched an anatomy video --24 Α Yes.

Page 118 Page 120 Q -- 17152. two years after her surgery? 1 1 2 A I see that, uh-huh. 2 A Yes. It still goes to the effort of Ethicon 3 3 in educating the people that are using their products. Q Do you know -- do you know what that is? 4 4 5 Q Let me -- let me make this simple. 5 Α The biocompatibility risk assessment towards 6 There's -- you obviously gave some opinions about 6 the bottom of the page. Q Okay. 7 warnings or the information that was provided in the 7 IFU and the patient brochure. 8 8 Obviously the FDA safety communication on the 9 9 A Right. second page. And then I think the rest are patient 10 Q We'll talk about that later, but you've given 10 brochures and IFUs, slide decks. That would be it. those opinions, correct? Nothing else on these three pages --11 11 12 12 A Yes. Α No. Q Or you set forth that you had seen the IFU 13 0 -- other than what you identified, plus the 13 IFUs, the patient brochures, and the side decks and the and seen the patient brochure; is that correct? 14 14 other materials you specifically identified? 15 A That's correct. 15 Q Okay. Other than the IFUs and patient 16 That's correct. 16 brochures that you've seen, on these three pages of 17 17 Okay. Now, if we go to the next page after Q 18 production materials, I need to know, is there anything 18 that, there's a list of two pages -- there's a list of else you can -- well, let me withdraw that. two pages that says "Other Materials." 19 19 Putting aside IFUs and patient brochures for 20 20 A Uh-huh. 21 a moment --21 Q Are those materials of significant to you --22 22 significance to you in forming your opinions? A Yes. 23 Q -- is there anything on these three pages of 23 A I'm reading through them. Obviously the FDA production materials that is significant to you in 24 Public Health Notification we've already talked about Page 119 forming your opinions, something where you'll say, 1 that, 2008, 2011, are important. The ACOG Frequently 1 "Well, that document is important to me in forming my Asked Questions, the committee opinion, AUA position 2 2 statement, I cited those. The IUGA Prolapse Guide for 3 opinions in this case"? 3 4 4 Women. ACOG Frequently Asked Questions again. The A Yes. AUGS position statement. ACOG committee opinion, the 5 Q So if you could just go through those three 5 pages and tell me. 6 6 AUA position statement. The Public Health Notification 7 7 is listed a couple times. The SGA -- SGS position A Okay. 8 8 statement. And that would be it before the Q We've already talked about the videos, so --9 9 case-specific list. 10 Q -- we don't have to talk about those again. 10 Q Okay. And you -- and that's including both 11 A Okay. 11 pages, right? Q But the rest, I just want to know if anything 12 12 Α That's both. 13 is of significance to you. 13 Q Because there's two materials on the second A Okay. The professional education slide 14 14 page. decks, the resource monographs, the surgical technique 15 15 Yes, that's both pages. Α 16 guides. I'm assuming you're considering the patient 16 Okay. The last thing on that list of other counseling guide as part of the patient brochures? materials is a June 2, 2006 Ethicon expert meeting, 17 17 18 Q Where do you see the patient counseling 18 meshes for pelvic floor repair. Did you even look at guide? 19 that document? 19 20 A I did not. If that relates to the consensus 20 A It's right before the videos. Q Oh, right. Is that something that you're 21 21 in the surgeon's monograph, that would be what I've looked at, but not this particular thing. 22 relying on? 22 23 23 Q But if there were meetings where Ethicon A Yes. 24 You realize that's a 2011 document, so it's 24 brought doctors and scientists together in 2006 and Q

Page 122 Page 124 2007 in Germany, you're not aware of that? Q (By Mr. Slater) Do you know, as you sit here 1 1 2 A I don't have those documents, no. 2 now, what criteria that committee opinion sets forth as 3 3 the appropriate patients to have a mesh kit like the O Correct? 4 4 Prolift put in their body? A No, I haven't reviewed them. 5 Q Okay. And then the last thing we have is the 5 A They support its use in high-risk patients. materials you looked at in connection with Ms. Hammons Q Do you recall how they define a high-risk 6 6 7 specifically, correct? 7 patient? 8 A I remember that they specifically state 8 A That's correct. 9 patients who have had recurrence, patients who have 9 Q There's a list of depositions. Did you read advanced degrees of prolapse. I don't remember beyond 10 all those depositions? 10 11 that. 11 A No. 12 Q Which did you read? 12 Do you know whether Patricia Hammons meets Q 13 A I read Dr. Baker's deposition, Patricia 13 the criteria in Committee Opinion 513, or do you need Hammons, Mike Heit, Dr. Lackey. Ann Weber is not on to see the committee opinion? 14 14 there, but I've read hers. And Dr. Zipper is not on 15 15 Α She does. here either, but I read his as well. And then 16 16 Okay. You think she does. Okay, that's 0 17 17 Dr. Drolet. fine. 18 Q You've read Dr. Drolet's report? 18 If, in fact, Patricia Hammons did not meet the committee opinion criteria, is it your opinion that 19 A I have. 19 20 she would not be a suitable candidate for the Prolift? 20 MR. SLATER: Okay, I was just handed 21 what I guess is the materials list dated 21 Α 22 November 12, 2015, which I guess is an 22 What was your criteria for the Prolift in Q 23 update. Can somebody mark that as an exhibit 23 terms of what patients you would offer it as an option 24 and give it to Dr. Lowman. 24 Page 123 Page 125 1 MS. DEMING: I'll need to go make a copy 1 Symptomatic pelvic organ prolapse. 2 of it, but I can do that and come back. 2 Q Any particular severity or grade? 3 3 MR. SLATER: Questioning while that's Α Not necessarily. 4 being done. We can come back to it. 4 Q Would you put a Prolift into a Stage 1 5 Q (By Mr. Slater) I want to ask you a question 5 prolapse? 6 about the AUGS/ACOG joint committee opinion, No. 513. 6 A If it were symptomatic. 7 That's one of the materials you said you relied on in 7 Did you ever put a Prolift into a Stage 1 Q 8 this case? 8 prolapse? 9 9 A Yes. A It's not usually symptomatic, so, no, I have 10 Q Okay. Do you agree with the conclusions that 10 not. But if it were, I would consider it. 11 are set forth in that committee opinion about what 11 O But you never did, right? patients are appropriate candidates for the use of mesh 12 12 Α No. 13 kits like the Prolift? 13 Stage 1 prolapse actually is considered a 14 MR. ISMAIL: Objection to form. 14 normal finding, right? 15 THE WITNESS: Do we have that available A I wouldn't call it normal. It's not normal 15 16 for me to look at? Do I have -- do you have 16 support, which is Stage 0. Stage 1 is mild prolapse. 17 that available for me to look at? 17 Q What percentage of women do you think are 18 MR. SLATER: No. I figured you knew it. walking around with a Stage 0? 18 I know it, so I just --A I'd guess maybe 10 percent. If you haven't 19 19 20 had children, the likelihood that you have Stage 0 is THE WITNESS: I don't know it --20 21 very high. Just -- it depends on the patient MR. SLATER: -- ask questions about 21 22 22 population that you're discussing. it. 23 THE WITNESS: I don't know it word for Percentage of women who have had children 23

would you think are walking around with a Stage 0?

24

24

word.

Page 126 Page 128 1 A If I had to guess, maybe 5 percent. MR. ISMAIL: Objection to form. 1 2 Q Now, is that a guess, or are you basing that 2 THE WITNESS: I believe there was an 3 on any study or clinical data? 3 update to the IFU either in 2008 or 2009, and 4 A I'm guessing, basing on my clinical 4 I believe that that would have been available experience, on my -- I'm basing that on my clinical 5 5 to him. 6 experience. 6 Q (By Mr. Slater) Do you know which patient 7 Q Would you agree there are many women who have 7 brochure Ms. Hammons testified that she saw? 8 Stage 2 prolapse and the symptoms are manageable and 8 A I don't. 9 they don't need surgery? 9 Q Do you know which patient brochure was --10 A Yes. 10 withdrawn. 11 Q Would you agree, in Patricia Hammons' case, 11 Do you know whether or not Dr. Baker that abdominal sacrocolpopexy was a reasonable 12 12 identified a patient brochure that he had seen and was 13 treatment option for her? relying on at the time he counseled and operated on 13 14 A Yes. 14 Ms. Hammons? 15 Q Would you agree with me that for Patricia 15 A He did remark about giving -- that it was Hammons, that a suture repair of her prolapse was a 16 likely that he gave her a patient brochure. 16 17 reasonable treatment option? 17 Q Do you know which one? 18 A That's a hard one for me to agree with. I'd 18 Α No. I don't believe he testified to that. 19 have to say no. 19 In drawing your opinions in this case, was it 20 O Understand my question. I'm not asking what 20 important to you to know which IFU was actually you would have done, but here's my question: Do you 21 21 available at the time that Dr. Baker counseled and agree with me that one of the reasonable options that 22 operated on Ms. Hammons? 22 23 could have been offered to Mrs. Hammons was a suture 23 MR. ISMAIL: Objection to form. repair of her prolapse? 24 THE WITNESS: No. Page 127 Page 129 1 MR. ISMAIL: Objection. Asked and 1 Q (By Mr. Slater) In forming your opinions in 2 2 answered. this case, was it important for you to know which 3 3 THE WITNESS: No. patient brochure Ms. Hammons actually saw? 4 MR. SLATER: Okay. 4 A No. 5 Q (By Mr. Slater) One of the materials on your 5 Q In forming your opinions in this case, was it 6 reliance list that you said is significant to you is 6 significant to you whether or not Dr. Baker actually 7 the surgeon's monograph, right? 7 saw the monograph? 8 8 A Yes. No. 9 9 Do you know which of the Prolift professional Do you know if it was available when 10 Dr. Baker was trained? 10 education slide decks was in use when Dr. Baker was A I believe so. Well, I don't know when he was 11 11 trained on the Prolift at an Ethicon event? trained. I know it was available before the procedure 12 12 A I don't. 13 that Mrs. Hammons had. 13 Q Was it of any significance to you -- well, 14 Q Okay. Do you know whether or not Dr. Baker 14 rephrase. ever saw the monograph? 15 Is it of any significance to you to know 15 16 A I don't know. 16 which professional education slide deck would have been utilized in Dr. Baker's training by Ethicon on the 17 Q Do you know whether or not the monograph was 17 available when Dr. Baker was trained? 18 Prolift? 18 19 A I don't know when he was trained. 19 A No. 20 20 Q Do you know which patient brochure --Q Do you know why Ethicon marketed the 21 rephrase. 21 Prolift+M? 22 Do you know which IFU was actually available 22 MR. ISMAIL: Objection to form. 23 to Dr. Baker when he counseled Ms. Hammons and operated 23 THE WITNESS: No. 24 on her? 24 Q (By Mr. Slater) Do you know why Ethicon

Page 130 Page 132 developed the Prolift M in order to be able to market on with the Prolift --1 1 2 2 Yes. it? Α 3 3 -- those 150 patients, do you know how many MR. ISMAIL: Objection to form. 4 THE WITNESS: I have an idea about some 4 of them had erosions? 5 of the concepts behind lighter weight mesh, 5 A I can't speak to that because I left my 6 if that's what you're getting to. I can't 6 fellowship program during part of what would have been 7 speak to what Ethicon was thinking. 7 the follow-up for some of them. I can say for the 8 Q (By Mr. Slater) It's your assumption that 8 approximately half that I operated on in -- while I've 9 Ethicon developed the Prolift+M because it was a 9 been at Kaiser, that there have been three erosions. 10 lighter weight mesh than the Gynemesh PS mesh? 10 O That you know of? A That's my assumption, yes. 11 11 Α That I know of. Do you agree that lighter weight mesh is You would agree with me that you may have 12 12 13 considered in the urogynecology community and 13 patients who had complications from a Prolift who literature to have safety advantages as against heavier didn't return to you but went to another doctor for 14 14 15 weight meshes? 15 treatment? 16 MR. ISMAIL: Objection to form. 16 A That's possible. That would be unlikely, 17 THE WITNESS: I believe that is a 17 though, because of the way that Kaiser is structured 18 theory, yes. 18 where patients have to see Kaiser doctors if they have 19 Q (By Mr. Slater) Do you agree with that? 19 Kaiser insurance, but it is possible. 20 Α No. 20 Q Well, it's possible that you operated on a 21 Q Do you think that the safety profile for a 21 patient with a Prolift, she had complications, and then heavyweight mesh or a mid-weight mesh is the same for whether or not you treated those complications, 22 22 23 that as a lightweight mesh? 23 eventually went to somebody else? 24 MR. ISMAIL: Objection to form. 24 A That's possible. Page 131 Page 133 1 THE WITNESS: No. 1 You can't say that hasn't happened, right? 2 2 Q (By Mr. Slater) Do you -- do you agree with MR. ISMAIL: Objection. Asked and me that a lightweight mesh is considered to be safer 3 3 answered. 4 than a mid-weight or a heavyweight mesh? 4 THE WITNESS: That's possible. 5 MR. ISMAIL: Objection to form. 5 Q (By Mr. Slater) Do you know any of the 6 THE WITNESS: No. 6 standards that Ethicon itself applied to whether or not 7 Q (By Mr. Slater) Do you have an opinion to a 7 the warnings and information provided in the IFU and reasonable degree of medical probability as to whether 8 the patient brochure were adequate? 8 9 or not there are any safety advantages as between the 9 A I don't know. Prolift M as compared to the Prolift? Do you have an 10 Q Do you know any of the standards that are 10 11 opinion one way or another on that subject? 11 applied in general to medical device manufacturers in providing information in an IFU or a patient brochure 12 A I do. 12 13 You fell out. I'm sorry. 13 in terms of what type of information should be Q Sure. What is your opinion? 14 supplied? 14 A My opinion is that there is a theory that 15 15 Α 16 lighter weight mesh might decrease the risk of 16 Q In giving your opinions as to whether or not complications with pelvic organ prolapse repair. the warnings and information in the IFU was adequate, 17 17 However, that has not been demonstrated in the 18 were you basing that on your own analysis of the 18 information and your own understanding of what 19 literature. 19 20 information you would need? 20 Q I asked you a little bit earlier about your own Prolift patients. I want to go back to that for a 21 21 Α Yes. couple of minutes. 22 22 Q In offering your opinions with regard to 23 23 whether the information provided in the patient A Okay. 24 With your -- with patients that you operated brochure was adequate, were you basing that upon your

Page 134 Page 136 MR. ISMAIL: Objection to form. own evaluation of what information you would personally 1 1 2 need in your practice? 2 THE WITNESS: Could you repeat the 3 3 A Yes. question? 4 4 Q Were you at all curious as to what standards Q (By Mr. Slater) Is that your assumption in 5 Ethicon felt it was bound to meet in terms of what 5 drawing your opinions in this case? 6 information and warnings would need to be provided to 6 MR. ISMAIL: Objection to form. Do you 7 physicians with regard to the Prolift? 7 need to hear back --8 MR. ISMAIL: Objection to form. 8 THE WITNESS: I need to hear back the 9 9 THE WITNESS: No. question. I'm sorry. 10 10 Q (By Mr. Slater) That was of no significance Q (By Mr. Slater) In drawing your opinions in this case with regard to whether the Prolift is safe or to you? 11 11 12 not --12 A No. 13 Q If I understand correctly, with regard to the 13 A Uh-huh. 14 O -- did you assume that when a woman would 14 warning opinions, those are based on your own have complications related to the Prolift mesh, that 15 evaluation of what information you would need in your 15 those complications could be safely and effectively practice; is that a correct statement? 16 16 17 A That's correct. 17 treated and the woman would then be okay going forward? 18 Q In your own practice, if Ethicon had 18 MR. ISMAIL: Objection --19 19 information that patients were experiencing very severe Q Is that your assumption with regard to 20 20 complications from the Prolift and that some of those mesh-related complications? 21 21 complications could not be safely and effectively MR. ISMAIL: Objection to form. treated and the women were being left with permanent 22 THE WITNESS: The majority of cases, 22 23 pain due to the Prolift itself, would you have wanted 23 yes. to have that information? 24 Q (By Mr. Slater) Did you assume that for some Page 135 Page 137 1 MR. ISMAIL: Objection to form. 1 women, that they could have Prolift mesh-related 2 THE WITNESS: Not necessarily. 2 complications that could not be safely and effectively 3 Q (By Mr. Slater) In drawing your opinions in 3 treated despite the best care and the women would be 4 this case with regard to the safety of the Prolift, did 4 left with permanent pain and permanent damage? 5 you assume that there are some women who have a Prolift 5 MR. ISMAIL: Objection to form. 6 put in their body and that due to the complications 6 THE WITNESS: Okay, you keep saying 7 with the mesh, they suffer injuries that are permanent 7 "assume," and I'm not sure what you're and life altering? Did you assume that that happens to 8 implying by that. Is it my opinion --8 9 some women due to the Prolift mesh? 9 Q (By Mr. Slater) As an expert --10 MR. ISMAIL: Objection to form. 10 I'm sorry. 11 THE WITNESS: No. 11 Q I'm asking, in drawing your opinions, what Q (By Mr. Slater) In drawing your opinions in facts you're assuming or what your understanding of the 12 12 13 this case, did you assume -- rephrase. 13 facts is --14 In drawing your opinions in this case with 14 A Okay. 15 regard to whether or not the Prolift is safe, was it 15 -- or are. 0 16 your assumption that if a woman has complications 16 Okay. related to the Prolift mesh, that those -- those So you draw an opinion based on facts that 17 17 18 complications can be safely and effectively treated 18 you believe exist, right? 19 such that the women will be okay going forward? 19 A That's correct. 20 MR. ISMAIL: Objection to form. 20 In drawing your opinions regarding the safety 21 THE WITNESS: That's been my of the Prolift --21 22 experience. 22 Α Uh-huh. 23 Q (By Mr. Slater) And is that your assumption 23 -- did you assume that if a woman has 24 in drawing your opinions in this case? 24 complications related to the Prolift mesh, that for

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Page 138
                                                                                                                Page 140
    some of those women, they can't be successfully treated
                                                                     A There's no way for me --
                                                             1
2
    and they can be left with permanent disabling pain and
                                                             2
                                                                         First it's just a yes or no. Would you be
3
    damage?
                                                             3
                                                                 able to tell me?
4
                                                             4
                                                                     A There's no way for me to tell you that, no.
           MR. ISMAIL: Objection to form.
5
           THE WITNESS: I didn't make any
                                                             5
                                                                     Q Let me ask you this: Did you personally add
                                                                 anything to this list because you thought it was
6
       assumptions in formulating my opinions about
                                                             6
7
       the Prolift. In my clinical experience,
                                                             7
                                                                 something that was important to you and significant to
       women that have had complications with the
                                                                 you in forming your opinions in this case?
8
                                                             8
9
                                                             9
                                                                     A If I added it to the list, most likely, yes.
       Prolift have been able to be successfully
                                                                     O Now, you have this list here. Is there
10
       treated.
                                                             10
                                                                 anything that you can identify for me on this list that
11
       Q (By Mr. Slater) So in evaluating the safety
                                                            11
    of the Prolift, you base that on your personal
                                                                 was added by you at your insistence because you felt
12
                                                            12
13
    experience with managing complications?
                                                                 like, "Oh, I left this off the list. I need to rely on
                                                            13
       A As well as the medical literature.
                                                                 this, it's important to me for my opinions, so I'm
14
                                                            14
15
           MR. SLATER: Do we have the updated
                                                                 adding it to the list"?
                                                            15
                                                                     A Okay, let me look through it. On the third
16
       reliance list yet in the room?
                                                            16
                                                                 page, the articles by Cobb. And I'm not -- I think the
17
           MR. GOODALL: Yes, we do.
                                                            17
18
           MR. SLATER: All right. Can we mark
                                                            18
                                                                 Feloa might be in addition. I don't remember
       that as whatever the next -- you know what,
19
                                                            19
                                                                 specifically.
       actually, don't mark it as the next exhibit
20
                                                            20
                                                                     0
                                                                         Which one?
       because I have a series that are premarked,
21
                                                            21
                                                                     Α
                                                                         The Feola article towards the end of that
22
       so just to be safe, let's mark it as Exhibit
                                                            22
                                                                 same page.
23
       22.
                                                            23
                                                                     Q Feola I have on the third -- I have on the
24
           (Exhibit 22 marked for identification.)
                                                            24
                                                                 next page.
                                                   Page 139
                                                                                                                Page 141
           THE WITNESS: Okay.
                                                             1
                                                                         There must be another one. The article title
1
        Q (By Mr. Slater) Okay, Doctor, I was provided
2
                                                             2
                                                                 is "Deterioration in Biomechanical Properties of the
    this list of updated -- well, rephrase.
 3
                                                             3
                                                                 Vagina Following Implantation of a High Stiffness
 4
            Doctor, what we've marked as Exhibit 22, can
                                                             4
                                                                 Prolapse Mesh."
5
    you tell me what that is?
                                                             5
                                                                     O Got it. You originally told me the Cobb
6
        A I believe that this is a supplement to my
                                                             6
                                                                 articles and I checked them. After that, the next one
7
                                                             7
                                                                 is Feola, right?
    reliance list.
                                                             8
8
        Q Did you prepare this supplement?
                                                                     A Yes, yes.
9
                                                             9
            Not by myself, no.
                                                                        Okay.
10
        Q Are there articles on this list that you have
                                                            10
                                                                     A I think my tobacco use article might be an
11
                                                            11
                                                                 addition. I'm not sure about the Peter Sand article.
    not read?
        A I've read most of these articles at some
                                                                 This is -- three, four, five, six, seven, eight, nine,
12
                                                            12
13
    point.
                                                            13
                                                                 ten. It's on the tenth page, the very top.
        Q Well, most. I'm asking, are there any that
                                                                     Q I see it. Okay.
14
                                                            14
    vou haven't read?
                                                                     A I need to keep up with the pages. I think
15
                                                            15
16
            There might be.
                                                            16
                                                                 it's three pages after the page we were just on.
        Q All right. This list looks like it is the
                                                                 Velemir -- no, I'm sorry, Walters, Urogynecology and
17
                                                            17
    prior list with some additions to it. Is that
                                                                 Reconstructive Pelvic Surgery, Third Edition.
18
                                                            18
19
    accurate?
                                                            19
                                                                     Q Okay.
                                                            20
                                                                     A And I think that's it.
20
        Α
           Yes.
21
        Q There's no way for me to know unless I go
                                                            21
                                                                     Q If you turn forward, there's the section of
    through it. Is there any way for you to tell me what
                                                            22
                                                                 materials list where you have -- it starts with
22
                                                                 "Document Description" after the -- after the
23
    was added to this list yesterday that I saw today for
                                                            23
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24

literature list. Do you see that?

the first time?

24

Page 142 Page 144 A Yes. Α Yes. 1 1 2 Q Was anything added to this list? 2 Then there's an "Other" section. Let me ask 3 3 you this: The expert reports, had you read them when A Let me look. you wrote your original report, or did you read them 4 Q And I'll ask the question differently. Was 4 5 anything added to this list that's of any significance 5 after you wrote your report? 6 to you in forming your opinions? 6 A I did not have available to me the reports of 7 A Okay. I don't see anything added to that 7 Julie Drolet or Dr. Klinge. The rest of them I had. 8 section that was important for me. 8 Q And you've already confirmed to me that the 9 9 report contains your opinions. Are there any other Q Then if we go to the list three pages forward opinions outside of the report that you formed based on that says "Publicly Available" at the top --10 10 what you saw after you wrote your report, or can I rely 11 A Uh-huh. 11 on your report for your opinions? 12 Q -- was anything added to that list that's of 12 any significance to you? 13 MR. ISMAIL: Objection to form. 13 THE WITNESS: I'm not sure I know how to 14 14 Not other than what we've talked about, no. 15 15 Then if we go to the depositions and answer that. exhibits, in comparing, it looks like they added 16 Q (By Mr. Slater) Getting at. As a lawyer, we 16 use the report to have an understanding of what Dr. Zipper's deposition? 17 17 18 Uh-huh. Yes. And Dr. Weber. 18 opinions the expert has so we can be prepared. 19 And Dr. Weber's deposition? 19 Q 20 Yes. 20 Q I just need to know, are there other opinions Α 21 Q Do you know if any medical records were 21 that you have that are not in the report? Before, you 22 22 told me they're in the report. added? A Oh, my --23 23 A I don't know. 24 Q Have you looked at any additional medical 24 Q I just want to know if there's anything else. Page 143 Page 145 records in the -- since the time you wrote your report, 1 A Yes, there are, because I was not privy to --1 2 or had you seen them all at the time you wrote the I didn't have Dr. Drolet's report or Dr. Klinge's 3 report? 3 report at the time, and I do have some opinions about 4 4 those. A I'd seen them all at the time I wrote the 5 report, I believe. There were some additional records 5 Q Let's go. Dr. Drolet, tell me your opinions. 6 given. I have not reviewed them. So what I had at the 6 A Do you want to ask me a question? 7 time of the report is what I reviewed. 7 Q Based on Dr. Drolet's report, what are those 8 Q Do you know what it was that you were given 8 opinions? 9 but you have not reviewed since you wrote the report? 9 A We can't -- you have to restate the question. 10 A There were some additional hospital records, 10 Q You said -- okay. You said that you have additional opinions based on Dr. Drolet's report. What 11 but I don't know what hospital they were from. 11 Q For your opinions because you haven't seen are those opinions? 12 12 13 them, correct? 13 A Well, if I had to identify one that stands 14 out in my mind that is different is that when I wrote 14 A Correct. Q I'm sorry. Okay, you heard me? my initial report, I talked about the fact that I felt 15 15 16 A Yes, I could read your lips. 16 like Mrs. Hammons might have interstitial cystitis 17 Q We're getting better at this. because Dr. Zipper noted that she had pain with 17 18 A Yeah. palpation of her anterior vaginal wall. Dr. Drolet did 18 Q They added at the end of this expert reports. not make that notation. So if that's not the case, 19 19 Have you read each of those expert reports? 20 then that diagnosis would be less likely. 20 A I have not read the report of Peggy Pence. Q Interstitial -- well, rephrase. Let me 21 21 Q The expert report of Ann Weber, was it -- was 22 22 withdraw it. it a single report that was written in this case, the 23 Are there any other opinions based on 23 24 one that you read? 24 Drolet's report?

Page 146 Page 148 No. A You know, there might be. I'd have to have Α 1 1 2 you ask me a specific question. That was one thing 2 Is that your testimony? Q 3 that I remember, but I --3 A That's my testimony. 4 O I'm not going to --4 Q Okay. Are you saying that interstitial 5 A That's what I remember. 5 cystitis is purely a clinical diagnosis without 6 observation of the inside of the bladder? 6 Q The way this works is -- I'm sorry, Doctor, 7 the way this works is I ask you what opinions you have. 7 A You -- interstitial cystitis is a clinical 8 A Okay. 8 diagnosis. There is a procedure called cystoscopy with 9 9 hydrodistention that is done in the operating room Q I'm not going to -- you know, so I need to under general anesthesia, which can be used to aid in 10 know. This is my chance to get notice. 10 that diagnosis. Office cystoscopy does not rule in or 11 Α 11 Q So are there any other opinions that you have rule out interstitial cystitis. 12 12 13 based on Drolet's report other than what you just told 13 Q Let me ask you a question. If somebody has interstitial cystitis and they have cystoscopy, there 14 14 15 are certain things that one would expect to see on the MR. ISMAIL: Objection to form. 15 THE WITNESS: Just opinions about the bladder wall on cystoscopy, correct? 16 16 A Not in office cystoscopy, no. 17 entire case, opinions about the patient's 17 18 pain, just anything? 18 Q Okay. Did any doctor ever diagnose MR. SLATER: I'm asking for new interstitial cystitis for Ms. Hammons? 19 19 opinions. I'm asking for new opinions, 20 20 A No. anything new beyond what's in your report 21 21 Q You said that you saw Dr. Klinge's report 22 based on reading Drolet's report. 22 after you submitted your report and that that -- I 23 THE WITNESS: I'd have to think about 23 think you said that that may have also triggered new 24 the report. opinions. Did it or did I misunderstand? Page 147 Page 149 MR. SLATER: Understand, Doctor, I'm not 1 Α Did that trigger new opinions? I don't think 1 2 2 going to trying to convince you to come up so, no. 3 with more opinions. I just want to know that 3 Q I'm just going through a few things to try to 4 when I'm done with the deposition --4 shorten this fun process. 5 5 THE WITNESS: Right. MR. SLATER: All right, can we -- if 6 MR. SLATER: -- I know what opinions you 6 you could, Jon, could we give Dr. Lowman 7 have. I'm not asking you to come up with 7 Exhibit 2. 8 THE WITNESS: I have the exhibit. 8 9 9 THE WITNESS: Right. I mean, that's the Q (By Mr. Slater) Doctor, I want to ask you 10 only think that I can think of that would be 10 one -- okay. Let me ask you a question. Have you published any articles in the peer-reviewed literature 11 different. 11 12 since your -- since your fellowship was done? 12 Q (By Mr. Slater) Let me ask you a question 13 about interstitial cystitis. 13 A I have not. 14 Now, this Exhibit 2 is an article titled 14 A Okay. "Pelvic Magnetic Resonance Imaging for Assessment of 15 Ms. Hammons has had cystoscopy, correct? 15 0 16 16 the Efficacy of the Prolift System for Pelvic Organ Prolapse," and you're listed as one of the authors, 17 There have been no findings on cystoscopy 17 through which a diagnosis of interstitial cystitis was 18 correct? 18 19 made, correct? 19 A That's correct. 20 Q You worked on this study during your 20 A That's not how interstitial cystitis is fellowship under Dr. Hale, correct? 21 diagnosed. 21 22 Q Doctors will not use a cystoscopic view of 22 Α That's correct. the inside of the bladder as part of the process of 23 This study and the conclusions were based on 23 diagnosing or ruling out interstitial cystitis? 24 MRIs performed on 10 patients, correct? 24

Page 150 A Yes. Did Dr. Hale participate in writing this 1 1 2 Q If you could, go to page E4. 2 article? 3 3 A Okay. A I wrote the article. I'm sure that I had him 4 In the "Comments" section in the center 4 to review the article before it was published. Q 5 column about halfway down the page, there's a sentence 5 Q I want to ask you a few questions about, that says that, "Minimal tissue reaction was observed 6 6 first, the body of the article. Right on the front 7 on postoperative MRIs which supported the inert nature 7 page, the right-hand column, the third column over -of the polypropylene mesh." Do you see that sentence? 8 8 A Uh-huh. 9 A Not yet. Yes, I see it. 9 Q -- about four lines down there's a sentence Q Are MRIs routinely used to evaluate patients 10 10 that says, "Its ergonomic design makes it easier to following mesh surgery? place the graft in traditionally 'hard to reach 11 11 places." Do you see that? 12 A No. 12 13 Q A little more than halfway down in the 13 A I do. "Comment" column in the middle of page E4, there's a 14 14 0 Did you write that sentence? sentence that says, "However, it certainly does not 15 15 I did. deem it to be 'safe.' Pain, fibrosis, mesh erosion, 16 Did Ethicon see this article before it was 16 0 17 and mesh contracture are complications that have been 17 published? 18 reported with vaginally placed mesh and may not depend 18 A I don't remember. on inflammation." Do you see that? 19 19 Did Ethicon have input into the language of 20 A I do. 20 this article before it was published? 21 Q Is that a statement that you stand by? 21 22 A I did not write that statement. 22 0 How do you know that? 23 Q You're one of the co-authors. Do you 23 Because I wrote it. Α 24 disagree with that statement? 24 Q Was the article -- well, let me ask you this:

Page 151

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A I would not have used the word that this doesn't mean it to be safe. I think that's misleading. Can you see pain, fibrosis, et cetera, yes, I agree with that part.

Q Each of those complications listed -- pain, fibrosis, mesh erosion, and mesh contracture -- are complications that occur in some women with the Prolift, correct?

A Correct.

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10 Q Let's go to Exhibit 3.

A Sorry. Okay. 11

Q Exhibit 3 is an article titled "Does the

Prolift System Cause Dyspareunia," and you're listed as one of the authors, correct?

Α Yes.

0 The order in which the authors are listed is significant; the most senior author who's generally the lead of the study is listed last, correct?

A The most senior author is listed last, yes.

O And that would be Dr. Hale here?

A Dr. Hale.

Q Okay. Is there any disclosure of conflict of

23 interest in this article?

A I don't see one, no.

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Do you know if Dr. Hale shared the article with Ethicon before it was published and accepted any of their input into the language?

A I don't know if he shared the information with Ethicon or not, but I'm the one that wrote this article and I'm responsible for that sentence.

Q When you said that "the graft can be placed in traditionally hard to reach places," where are you talking about?

A I'm talking about the fact that the mesh spans from arcus to arcus and provides almost a paravaginal-like repair in doing that. It's very difficult to do a paravaginal repair vaginally. It's hard to see those spaces. And with the Prolift, the way that it's designed, you don't have to see them.

Q Are you talking about the places where the arms can be placed?

A No. I'm talking about -- I do think that it applies in that situation as well, but I'm talking about the way that the mesh spans in the anterior compartment, the mesh is designed to go from what we

22 call arcus to arcus, and in -- and in doing so, it

provides a paravaginal defect repair. It's difficult 23

to do that vaginally, and with the Prolift, it's

Page 152

39 (Pages 150 to 153)

Page 154 Page 156 easier. Q I'm about -- just below where I just read, 1 1 2 Do the arms and the use of the cannula and 2 maybe about 10 lines further down, 12 lines further Q 3 3 guide system enable one to be able to get the body of 4 the mesh to go arcus to arcus? Does that help to MR. ISMAIL: In the next paragraph. 5 enable that? 5 THE WITNESS: Next paragraph. 6 A Yes. 6 MR. SLATER: And it's -- the references 7 Q It does that because the arms get pulled out 7 to that sentence are 12 and 14. 8 through the exit points and that helps to pull the mesh 8 THE WITNESS: Yes, I see it. 9 9 out and span that area within the pelvis that you just Q (By Mr. Slater) And those references, 12 and described, correct? 10 10 14, include an article. No. 12 is by members of the A That's correct. French TVM group, correct? 11 11 12 12 Okay. And those are areas that are difficult A That's correct. to reach with conventional surgical techniques, 13 They're the people that developed and 13 invented the Prolift system, correct? 14 correct? 14 15 15 A That's correct. Α That's correct. Q Therefore, when one has complications with 16 Q So you're citing the inventors of the Prolift 16 the mesh in those areas, those are difficult to reach 17 for the proposition that there is concern that the rate 17 18 areas to treat those mesh complications, correct? 18 of de novo dyspareunia with this procedure may be 19 A You don't -- you don't need to reach those 19 unacceptably high, correct? 20 same areas that the trocars are traversing. Usually 20 A That's correct. 21 areas that are causing the patient's pain are palpable 21 Q This "Materials and Methods" section of this 22 transvaginally, and if you're able to transect or 22 article says that all cases of Prolift performed 23 release tension in that area, then it's not necessary 23 between August 2005 and August 2007 were evaluated. 24 to kind of get out to those same spaces. 24 Those are cases that were performed on patients during Page 155 Page 157 1 Q Are you aware that the mesh can contract 1 your fellowship? 2 anywhere within the pelvis, including in areas where 2 Α Yeah. 3 it's difficult to operate through conventional 3 Q Were you personally involved in each of those 4 techniques? 4 procedures? 5 5 MR. ISMAIL: Objection to --Not in all of them, no. 6 THE WITNESS: Yes. 6 Q On page E2, in the left-hand column, about 7 MR. ISMAIL: -- form. 7 eight lines down, it says, "The rate of de novo 8 THE WITNESS: Sorry. 8 dyspareunia was calculated using chart review and 9 Q (By Mr. Slater) And are you aware that that 9 telephone interview." That's what it says, correct? 10 contraction can lead to pain for the patient? 10 A Yes. 11 A Yeah. 11 Q And I've read through the article, and it Q Do you know whether Ethicon, in designing the appeared to me that the way that you calculated these 12 12 13 Prolift, made any effort to come up with a way to treat 13 numbers ultimately was you did a chart review and, complications when women would suffer complications based on what was documented in the chart, calculated 14 the percentages and the figures you came up with; is related to the mesh? Do you know if Ethicon even 15 15 16 looked at that issue? 16 that correct? MR. ISMAIL: Objection to form. 17 17 Α And telephone interview, yes. 18 THE WITNESS: I don't know. 18 Q What -- the telephone interview, what did Q (By Mr. Slater) On the first page just below that entail? 19 19 where we just read, there's a sentence that says --20 20 A I'm trying to recollect that. If I remember it's the first full paragraph -- "There is concern, correctly, I believe that the telephone interview was 21 21 however, that the rate of de novo dyspareunia with this specifically for patients that we had incomplete data 22 22 procedure may be unacceptably high." Do you see that? 23 on, to try to get a better picture of who actually had

dyspareunia and who didn't if they hadn't followed up.

24

23 24

A I'm sorry, where did you say you were?

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Page 158
                                                                                                                   Page 160
        Q I'm looking at the left column on page E2 and
                                                               1
                                                                      A In 2008, I believe.
1
2
    then over to the center column. And what it appears to
                                                               2
                                                                          Am I correct that you presented this abstract
3
    me from reading it is that you had the data you had
                                                               3
                                                                  at the Society of Gynecologic Surgeons, and subsequent
4
    from the chart review and then you contacted people and
                                                               4
                                                                  to that your article was published in American Journal
5
    asked them if they were willing to answer
                                                               5
                                                                  of Obstetrics and Gynecology?
                                                               6
6
    questionnaires; and if they were willing to do it, you
                                                                      Α
                                                                          Yeah.
7
    sent the questionnaires to them to potentially
                                                               7
                                                                      0
                                                                          Am I correct about that?
    supplement the information that you had obtained
8
                                                               8
                                                                      Α
                                                                          Yes.
9
    through the chart review. Is that accurate?
                                                               9
                                                                      Q And when you -- rephrase.
10
           MR. ISMAIL: Objection to form. If you
                                                              10
                                                                          When you presented this data, did you present
11
        need to read it, you can.
                                                              11
                                                                  it at a meeting to other doctors?
12
           THE WITNESS: Yeah, let me read it.
                                                              12
                                                                      A Yes, at the Society of --
13
           Yes, so I believe that I did the
                                                              13
                                                                          And when you presented, were -- okay. And
                                                                  when you presented, were you on the stage with several
14
        telephone interview to confirm those that
                                                              14
                                                                  other physicians who were also presenting data and
15
        were sexually active so that we could send
                                                              15
                                                                  findings about the use of mesh?
        them the questionnaire, those that were
                                                              16
16
17
        sexually active and willing to participate.
                                                              17
                                                                      A Yes.
18
        Q (By Mr. Slater) Based upon the data from the
                                                              18
                                                                          MR. ISMAIL: Restate, please.
19
    chart review -- well, rephrase.
                                                              19
                                                                      Q (By Mr. Slater) Do you recall what other
20
           The chart review means that after treating
                                                              20
                                                                  physicians were presenting with you during that
21
    the patients, you went back and looked at those medical
                                                              21
                                                                  presentation, who else was on stage with you?
    charts to take the information from the medical chart
                                                              22
22
                                                                      A I don't.
23
    and that's how you calculated the numbers ultimately,
                                                              23
                                                                          One name of one of the doctors you presented
                                                                      Q
24
    correct?
                                                              24
                                                                  with at SGS?
                                                    Page 159
                                                                                                                   Page 161
1
       A That's part of it, yes.
                                                               1
                                                                         I can't. I don't remember.
2
        Q In terms of the dyspareunia numbers, that's
                                                               2
                                                                      Q Big day for you, you're a fellow, you're
3
    where you got the data that came to the 16.7 percent
                                                               3
                                                                   going to present at SGS on a study, I mean, this must
4
    de novo dyspareunia rate, correct?
                                                               4
                                                                  have been a big day, right?
                                                               5
5
       A Yes.
                                                                      A It was a big day.
6
        Q
           Going by the chart review, tell me if I'm
                                                               6
                                                                      Q And you can't remember what other doctors
7
    correct, that ultimately there were 57 women who were
                                                               7
                                                                  were on the stage with you that day?
    sexually active at the start, 21 of them preoperatively
                                                                      A No. I was never told that I was going to be
8
                                                               8
9
    had dyspareunia, so you excluded them to get down to 36
                                                              9
                                                                   on the stage with other doctors. That was a surprise.
    women for evaluation, and six of those 36 women, based
                                                              10
                                                                      Q But then you got up there. Were they -- but
10
11
    on chart review, had de novo dyspareunia, and that told
                                                              11
                                                                  you were with other doctors on the stage. Were they
    you that it was 16.7 percent, correct?
                                                                   people that you respected?
12
                                                              12
13
       A Yes.
                                                              13
                                                                      A I didn't know who they were.
14
        Q The article says -- well, let me withdraw
                                                              14
                                                                      Q Your involvement with SGS, was that
    that. Let me just figure something out here.
                                                                  facilitated at all through Miles Murphy?
15
                                                              15
16
           MR. SLATER: Okay. If we could, can we
                                                              16
                                                                      Α
                                                                          No.
17
        mark the abstract for this as the next
                                                              17
                                                                      Q
                                                                           Now, let's look at the abstract of the
```

41 (Pages 158 to 161)

presentation you made at the Society of Gynecologic

questionnaires that were filled out by the patients and

function questionnaire known as the PISQ-12; is that

Surgeons that we've marked as Exhibit 23. If I'm --

tell me if I'm correct. You based this data on the

specifically a validated condition specific sexual

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19

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correct?

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exhibit, which I guess would be up to 23.

THE WITNESS: Okay.

presented where?

(Exhibit 23 marked for identification.)

Q (By Mr. Slater) Okay. The abstract was

A At the Society of Gynecologic Surgeons.

Okay. And when was it presented?

Page 162 Page 164 A Yes, that's correct. abstract was sent and my presentation. I do not 1 1 2 Q And it's a validated questionnaire, meaning 2 remember presenting a de novo dyspareunia rate of 3 it's accepted in the urogynecologic community that the 24 percent. So I'm suspecting that the classification 3 questionnaire questions and the responses that one gets error was discovered before presentation. So I do not 4 4 5 to them can be relied on, correct? 5 think that I presented a dyspareunia rate of 24 6 6 A Yes, that's correct. percent. 7 And based on the questionnaire responses, you 7 Q Doctor, there's no classification error here. calculated a rate of 24 percent de novo dyspareunia, 8 8 What are you -- what is a classification error? 9 9 MR. ISMAIL: Objection. 10 A Let me look at that. 10 THE WITNESS: That --11 11 Q There in the conclusion, bottom right. MR. ISMAIL: Move to strike. 12 A It looks like that, yeah. 12 MR. SLATER: I'll withdraw the question. 13 Q So that percentage was significantly higher 13 Q (By Mr. Slater) Let me walk you through what than the percentage that you put into your published happened, okay? If you look at your data --14 14 article about this study when you decided to rely on 15 15 A You're going to walk me through what the chart review instead, right? 16 happened? 16 17 MR. ISMAIL: Objection to form. 17 Q Yeah, I'm going to -- yeah, Doctor, I'm going 18 THE WITNESS: No. What I'm suspecting 18 to walk you through it. 19 is that -- well, you know, I don't know. Let Okay. 19 me just look at this quickly. 20 20 When you did -- when you originally did your abstract, you based it on the results from the 21 MR. SLATER: Let's change --21 22 MR. ISMAIL: Hold on. 22 questionnaires, correct? 23 THE WITNESS: Let me just look at it, 23 A I based it on the results from chart review and questionnaires and telephone interview, yes. 24 please. I'm wondering if there may have been 24 Page 163 Page 165 1 a misclassification error, because in the 1 Q Well, the data that was reported in the 2 actual paper, it says that 129 cases of 2 abstract, the 24 percent number, that came from the Prolift were performed, and in the abstract, 3 3 result of the questionnaires --4 it says that 128 Prolift cases were 4 A That's correct --5 5 performed, and that may have affected that -- correct? 6 number. 6 A -- but as I said before, there was 128 cases 7 MR. SLATER: Let's change the tape --7 that were evaluated for the abstract. In the paper and THE VIDEOGRAPHER: We are now going off 8 8 in the presentation, there were 129 cases. So we must 9 9 have missed a patient. That's why the number is the --10 10 different. MR. SLATER: -- because it's running 11 11 Q I'm going to walk you through some numbers, out. and you're going to tell me if I have the numbers 12 THE VIDEOGRAPHER: We are now going off 12 13 the video record. The time is currently 13 right, okay? 3:08 p.m. This is the end of Tape No. 3. 14 A Okay. Are you looking at the abstract? 14 15 (Recess taken.) 15 Q I'm looking at both. I've been through them 16 THE VIDEOGRAPHER: We are now back on 16 both pretty thoroughly. the video record with Tape No. 4. The time A Okay. 17 17 18 is currently 3:19 p.m. 18 Q Fifty-six women agreed originally to fill out Q (By Mr. Slater) Doctor, just to confirm, you the questionnaires. Eventually 41 of those 56 women 19 19 presented at SGS on your study of Prolift patients from responded to the questionnaires, correct? 20 20 your fellowship and reported at that meeting, A I have to -- are you looking at the abstract 21 21 consistent with your abstract, a 24 approximate de novo or the paper? At some point, the numbers changed. So 22 22 dyspareunia rate, correct? 23 I need to know which one you're looking at. 23 24 A I don't know the time frame of when this 24 Q Let me see. Okay. Look at the article.

Page 166 Page 168 A Okay. A No. The way that I calculated it is 1 1 2 Q We can look at your published article. 2 what's --3 3 Α O Wait, let me withdraw it --4 O The right-hand column of the "Results" column 4 A -- the summary numbers. 5 on page E2. 5 -- because I just missed -- Doctor, Doctor, 6 A Uh-huh. 6 Doctor, I misspoke, so I want to just get a clean question, okay? 7 Q And what it says here halfway down is, 7 8 "Fifty-six of the sexually active patients agreed to 8 A Okay. 9 9 answer questionnaires. The response rate was 73 Q Here's a calculation. Twenty-one women had 10 percent, meaning 41 women actually responded to the 10 dyspareunia postoperatively, eight of whom also had it questionnaires," correct? at baseline preoperatively, correct? 11 11 12 A Uh-huh. 12 A Let me just see that. 13 Q It says, "Twenty of the 41 sexually active 13 MR. ISMAIL: Objection to form. patients who responded to the questionnaires described 14 14 MR. SLATER: Okay. themselves as pain-free." THE WITNESS: Yeah, I think that's 15 15 correct. I mean, I go through a bunch of 16 A Okav. 16 17 Q And then if you go further down, we know that 17 numbers here. The bottom line is that there 18 there's 21 patients who reported dyspareunia, correct? 18 were --19 A That's correct. 19 MR. SLATER: Doctor, I'm going through 20 Q Okay. Now, if you go further to the bottom 20 this the way I'm going through it. I don't 21 of the page, of the 21 patients who reported 21 want to know your bottom line right now. dyspareunia, 38 percent, 8 out of 21 -- it goes 22 THE WITNESS: Okay. 22 23 through -- describe their pain as mild, 8 of 21 is 23 MR. ISMAIL: Move to strike. moderate, and 5 of 21 is severe. Do you see that? 24 Q (By Mr. Slater) Okay. So let's do this. We Page 167 1 A I do. 1 have a set of 41 women, correct, 41 women responded to 2 2 Q Okay. Now, on page E3, at the top of the the questionnaires, right? first paragraph, it says, "Eight respondents reported 3 3 A I believe that's correct, yes. 4 dyspareunia at baseline, leaving 13 with de novo 4 Q The prior page, E2. 5 dyspareunia by retrospective self-report." That would 5 Α Yes. Okay. Eight of those women preoperatively 6 be the questionnaire, correct? 6 Q 7 A Yes, that's what it says, uh-huh. 7 had dyspareunia, so you're going to drop them out of 8 the set because you're not looking to measure women 8 Q Reported dyspareunia, eight of which said 9 9 that already had dyspareunia, you want to know women they had it preoperatively, correct? 10 A Eight said that they had dyspareunia at 10 who were pain-free at baseline, correct? 11 baseline, which would mean preoperatively, yes. 11 A Correct. Q Okay. And since you're trying to evaluate Forty-one, which is the denominator, you 12 12 Q 13 de novo dyspareunia, you then subtract the eight who 13 would subtract those eight out and that would be had it preoperatively from the 21, correct? 14 33 --14 15 15 That's correct. But where are you seeing the eight? Α Α 16 Q And what you also do when you're trying to 16 Q -- and then 21 --17 get a percentage is you then also subtract eight from 17 Where did the eight come from? Α the 41 so that your numerator and denominator will be 18 On page E3, the first full paragraph in the 18 19 left column, eight respondents reported dyspareunia at 19 consistent, so you have -- you have 13 women with 20 baseline, leaving 13 with de novo dyspareunia. de novo dyspareunia out of a set of 33 women. That 20 becomes how you would calculate this, correct? 21 A By retrospective self-report. 21 The questionnaire we're talking about, right? 22 MR. ISMAIL: Objection to form. 22 Q 23 Q (By Mr. Slater) Eight out of -- eight out of 23 That's correct, but the questionnaire wasn't 24 33, correct? 24 the only thing we used. We were also using chart

Page 170 Page 172 review. Patients sometimes -like I said, I have to --1 1 2 Q Doctor, I'm only doing -- holy moly. Doctor, 2 Q Okay. 3 I'm not asking about --3 A -- look through all of this to make sure that A I've outlined in this --4 the numbers that you're saying are right. What I 4 5 Q I'm calculating -- Doctor, I'm calculating 5 published is right. 6 the results based on the questionnaire right now. 6 Q Doctor, I'm accepting your numbers. 7 A Okay. The questionnaire was not the only --7 Α Okay. 8 Q And then we'll talk through all the different 8 Q I'm accepting the number of eight women, 9 9 okay, so -- and I think I understand what you just statistics. 10 10 A The questionnaire was not the only thing we said. In order to determine the preoperative 11 dyspareunia rate, you used the questionnaires and you 11 used. 12 cross-checked with the chart review? 12 Q It doesn't matter. I realize that, Doctor. 13 Do you understand that one of the things I can do if 13 A Exactly. you testify in this case in a public courtroom is 14 Q Okay. So the number of eight you were able 14 attack the validity of how you came to the numbers you to double-check and get yourself more confidence and 15 15 publicly recorded? you were able to say eight women had preoperative 16 16 17 17 A I understand that. dyspareunia, correct? 18 Q Well, we're going through that process right 18 MR. ISMAIL: Objection to form. 19 19 now, with all due respect. THE WITNESS: Of the patients that 20 20 A Okav. responded by self-report, yes. 21 Q So there were 41 women total that responded, 21 Q (By Mr. Slater) Okay. So all I want to do eight of them had preoperative dyspareunia, right? 22 is tell me if these numbers are accurate. You have a 22 23 A I think that's correct. I have to go through 23 denominator of 41 women and a -- and a numerator of 21, 24 and write this all out. 24 meaning 21 out of 41 women reported dyspareunia on the Page 171 Page 173 1 Q Right there, the full -- first full paragraph 1 questionnaires, correct? 2 2 on page E3. I've shown it to you three times. A Are you talking about preop dyspareunia or 3 A It says --3 postop dyspareunia? 4 Q Eight women had preoperative dyspareunia. 4 Q Postoperatively, postop on the 5 5 A That's correct. questionnaires. 6 Q And we've already established that post --6 A You know what, let me look at something else 7 when they filled out the questionnaires, 21 women 7 that I have here. 8 8 reported dyspareunia, correct? Q It's right on page E2 --9 9 A Twenty-one patients reported dyspareunia, Α Uh-huh. 10 10 Q -- in the bottom right-hand corner paragraph that's right. 11 Q Okay. So if you want to only evaluate 11 where it says, "Fifty-six of the sexually active de novo dyspareunia, you subtract eight from the patients agreed to answer questionnaires. The response 12 12 13 numerator of 21 and you subtract eight from the 13 rate was 73 percent, meaning 41 responded." denominator of 41, correct, so you're excluding those 14 14 Uh-huh. 15 eight women from your calculation, correct? That's a 15 So we know we have a set of 41 women that 0 16 way to do this, right? 16 responded. 17 17 A Like I said, we did not determine who had A Okay. 18 dyspareunia at baseline and who had dyspareunia after 18 Q Then it says, "Twenty of the 41 sexually surgery solely based on the questionnaires. We also active patients who responded to the questionnaires 19 19 20 went through chart review. Patients sometimes don't describe themselves as pain-free." So 20 out of 41 had 20 21 recollect whether or not they had dyspareunia before no dyspareunia, and that leaves 21 at the bottom of the 21 22 surgery or not. If they documented dyspareunia before 22 page right there -surgery and that was discordant with the 23 23 Α Uh-huh. 24 questionnaires, then we would defer to the chart. So 24 -- who reported dyspareunia?

Page 174 Page 176 A That's correct. dyspareunia rate of 24 percent is a high rate, correct? 1 1 2 Q So 21 out of 41 reported dyspareunia on the 2 A That's correct. 3 3 Q When you published the article, which we've questionnaires, correct? marked as Exhibit 3, if you look at the last page of 4 A That's correct. 4 5 Q Okay. If you want to then eliminate the 5 your article, you made a finding in the bottom left 6 women who had dyspareunia at baseline because you're 6 column over to the center column --7 trying to evaluate preoperative -- rephrase. 7 A On what page again? Q -- that --8 If you're trying to eliminate the women who 8 9 9 had dyspareunia at baseline because you're trying to A I'm sorry. 10 study de novo dyspareunia, you would subtract those 10 Q Page E5. eight women from both the numerator and the 11 11 Α Okay. denominator, right? 12 12 Q You made a finding -- in the bottom of the 13 A That's correct. 13 left column and the bottom of the center column, you 14 Q Right, so it would be -- on the numerator, 21 14 talk about it -- that you decided chart review provided minus 8 would be 13, and 41 minus 8 would be 33, 15 15 a more valid calculation rather than a retrospective correct? questionnaire assessment. That was the decision you 16 16 17 A You said 18 and 33? 17 made, so you decided to rely on the chart review 18 Thirteen and thirty-three. 18 without reference to the questionnaires in reporting 19 MR. ISMAIL: Restate. 19 16.7 percent, correct? 20 Q (By Mr. Slater) Twenty-one minus 8 equals 13 20 A Let me just read this, please. Okay, yes, I 21 and 41 minus 8 equals 33, correct? 21 did conclude that. 22 A I think that's correct. Math is not my 22 Q If you had reported the de novo dyspareunia 23 23 rate that the patients reported on the questionnaires, strong point. 24 Q Okay. I took out my calculator on my handy 24 while using the chart review as a check on the Page 175 Page 177 iPhone and divided 13 divided by 33 to see the 1 preoperative dyspareunia that was actually reported 1 2 2 percentage of de novo dyspareunia, and I came up with when the patients came in, the percentage is what I 39.4 percent based on the questionnaires and using the 3 gave you, 39.4 percent, correct? 4 chart review to establish who had dyspareunia at 4 A Ask that question again. 5 5 baseline. Q Decided to report in your published article 6 MR. ISMAIL: Objection. 6 the rate of de novo dyspareunia based on the results of 7 Q (By Mr. Slater) Will you accept 39.4 percent 7 the questionnaires while cross-checking with the chart 8 to determine the preoperative -- the preoperative 8 as an accurate calculation? 9 9 dyspareunia rate, we've gone through it, the rate would MR. ISMAIL: Objection to form. 10 THE WITNESS: No, that's what I'm 10 have been 39.4 percent, correct? 11 saying, we didn't use just the 11 MR. ISMAIL: Objection to form. questionnaires. I can't agree --12 THE WITNESS: I believe that's 12 13 Q (By Mr. Slater) Thirteen divided by 33 -- 13 13 incorrect. From what I'm understanding from divided by 33 is 39.4 percent, will you agree to that 14 14 what I wrote here is that there was a percentage --15 15 discrepancy between what we found with chart 16 A Yes. 16 review versus what we found with the 17 questionnaires. And there were six patients 17 -- that the calculation is accurate? Okay. 18 Okay. Now, what you did, as well, is you 18 who reported de novo dyspareunia by chart then went to -- rephrase. review on telephone interview and then 13 by 19 19 In the abstract, you reported 24 percent 20 questionnaire. And so we decided that the 20 de novo dyspareunia rate, which you described as a high most objective evaluation was chart review 21 21 rate in the abstract, correct? 22 22 because it was an objective assessment and we 23 23 weren't asking people to recollect. A That's correct.

(By Mr. Slater) Doctor, the charts were

24

24

Q

And you would agree with me that a

Page 178 Page 180 filled out by the doctors who were treating the questionnaires that were sent to patients and filled 1 1 2 patients, right? 2 out by 41 women, correct? 3 3 MR. ISMAIL: Objection to form. A No, that part of the chart was filled out by 4 4 THE WITNESS: No, we didn't disregard the patient. 5 Q I'm talking about chart review. You're 5 them. But when it came to classifying saying that there were independent questionnaires in 6 6 patients as having de novo dyspareunia, we 7 the medical chart? 7 used their baseline complaint of, you know, whether or not they had dyspareunia or not, 8 A Yes. 8 9 9 Q These aren't medical charts that the patients versus a questionnaire that asked them to 10 were having their results tracked in? 10 recollect whether or not they had dyspareunia A We have a patient questionnaire that is part or not before surgery. 11 11 12 (By Mr. Slater) With regard to whether they 12 of the medical record. Q And that questionnaire was filled out at 13 had dyspareunia postoperatively, you decided to rely on 13 baseline in order for them to document their 14 the chart and disregard what they wrote in the 14 validated questionnaires, correct? 15 preoperative condition, correct? 15 MR. ISMAIL: I think you just stated 16 A Correct. 16 that backwards. Try that again. 17 Q Right? 17 18 MR. ISMAIL: Restate, please. 18 Q (By Mr. Slater) When you then reported in Q (By Mr. Slater) That is what you're your published article and came to your percentage of 19 19 referring to by what the patients filled out in the 16.7 percent, that was based on the complaints of 20 20 21 chart, correct? 21 de novo dyspareunia in the chart and it disregarded 22 A Correct. 22 what was reported in the validated questionnaire, 23 Q The rest of the medical chart is the findings 23 correct? of the doctors and what's recorded in the medical chart 24 MR. ISMAIL: Objection to form. Page 179 Page 181 while they're patients, correct? 1 THE WITNESS: No. We only deferred to 1 2 2 A Correct. the chart if there was a discrepancy between 3 Q And the number of women who had dyspareunia 3 the -- in the information. following the surgery based on chart review was what 4 4 Q (By Mr. Slater) Your article and it seems to 5 was documented in the chart by the doctors who were 5 be saying to me that you relied on the chart review for 6 treating the patients, correct? 6 these de novo dyspareunia numbers. That's what it says 7 MR. ISMAIL: Objection to form. 7 here in the bottom of the page on E5. 8 THE WITNESS: Not completely. There 8 A The bottom of the page where? 9 9 are -- when we have -- see our patients back, Q In fact -- yeah, the bottom of the left 10 they fill out a short patient questionnaire 10 column, "We therefore calculated the de novo dyspareunia rate by chart review, which allowed an 11 as well. So there's patient -- what do you 11 objective preop and postop assessment of all sexually 12 call it -- patient information that the 12 13 patient responds to in addition to our 13 active patients." findings as well. So when patients come for 14 A Right, and we explained --14 15 an office visit, they're usually given a That's what you wrote in the article. 15 16 small -- because it's -- it was an academic 16 A That's what I just said. If there was a 17 practice, so we tried to incorporate discrepancy, we relied on the chart review because 17 18 standardized questionnaires to be able to do 18 that's a more objective assessment that is not subject research. So patients gave us subjective 19 to recall bias, as I describe in that paragraph. 19 20 assessments at each -- at each -- at each 20 Q Where does it say, "If there was a 21 discrepancy, we relied on the chart review; and if visit. 21 there wasn't a discrepancy, we relied on the 22 Q (By Mr. Slater) Ultimately you made a 22 decision that you were going to rely on the chart 23 questionnaire"? 23 24 review and you were going to disregard the validated 24 A It says, "Interestingly, assessing

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Page 182
                                                                                                                   Page 184
    dyspareunia by two different methods led to two
                                                                   moment ago that 17 percent is high, right?
1
                                                               1
   different results." That means there's a discrepancy.
                                                               2
                                                                          That's correct.
2
    There were six patients who reported de novo
                                                               3
                                                                          Okay. So Prolift patients, based on your own
3
    dyspareunia by chart review in telephone interview and
                                                               4
                                                                   study, have a high postoperative de novo dyspareunia
4
5
    13 by questionnaire. So that's the discrepancy.
                                                               5
                                                                   rate, correct?
                                                               6
6
    The --
                                                                          MR. ISMAIL: Objection to form.
7
                                                               7
                                                                          THE WITNESS: That's incorrect.
        Q
           Okay, I got what you're saying. I got it.
8
    Okay.
                                                               8
                                                                          MR. SLATER: Okay. We'll try it in
9
                                                               9
                                                                      court, then, and we'll see how it goes.
        Α
            Yeah.
10
            The number -- the numbers were different and
                                                              10
                                                                          THE WITNESS: Let's go.
11
    you chose the lower numbers ultimately, right?
                                                              11
                                                                          MR. SLATER: Okay.
                                                              12
                                                                          THE WITNESS: I mean, this is 2015.
12
           MR. ISMAIL: Objection to form.
13
           THE WITNESS: We chose the numbers that
                                                              13
                                                                      This was in 2008. We've learned a --
                                                                          MR. SLATER: Okav.
14
        we thought were more objective.
                                                              14
                                                              15
                                                                          THE WITNESS: We've learned a lot since
15
        Q (By Mr. Slater) Those happened to be the
    lower numbers, right?
                                                              16
16
                                                                      then.
17
        A They happened to be lower.
                                                              17
                                                                          MR. SLATER: We have, except you don't
                                                                      know why the Prolift isn't being marketed
18
        Q And, in fact, just to understand where the
                                                              18
19
    24 percent came from, just below what you just read,
                                                              19
                                                                      anymore, right?
20
    you indicated that 5 percent of patients who reported
                                                              20
                                                                          THE WITNESS: That's correct, I do not.
21
    immediate postop dyspareunia reported that it resolved
                                                              21
                                                                      It should be.
22
    at the time of chart review.
                                                              22
                                                                      Q (By Mr. Slater) What if the Prolift wasn't
23
           When I did these calculations and it was 13
                                                              23
                                                                   being marketed because internally they were concerned
24 over 33, you cut those out of the -- of the numerator
                                                              24
                                                                   about the dyspareunia rate, would that matter to you?
                                                    Page 183
                                                                                                                   Page 185
    so that it was 8 out of 33, which comes to the 24
                                                               1
                                                                         MR. ISMAIL: Objection to form.
1
                                                               2
                                                                         THE WITNESS: No.
    percent. That's how you got to 24 percent, right? You
                                                               3
                                                                      Q (By Mr. Slater) What if the Prolift wasn't
    actually cut out the people whose complaints resolved
4
    in the short term, right?
                                                               4
                                                                  being marketed because Ethicon was worried that so many
5
       A I don't know. I'd have to look at it, but
                                                               5
                                                                  women were being harmed that they couldn't ethically
6
   I'll take your word for it. I don't think it matters.
                                                               6
                                                                  leave it on the market anymore, would that be
7
    Twenty-four percent -- if you want to say 24 percent,
                                                               7
                                                                  significant to you?
    that's fine. Nobody was impressed by a low number when
                                                              8
                                                                         MR. ISMAIL: Objection to form.
    I presented this paper. A dyspareunia rate of 17
                                                              9
                                                                         THE WITNESS: No.
9
    percent is high -- is just as high as 24 percent, so if
                                                              10
                                                                      Q (By Mr. Slater) What if one of the top
10
    you want to say it's 24 percent, that's fine. The
11
                                                              11
                                                                  medical directors in all of Johnson & Johnson said that
    dyspareunia rate --
                                                                  a reasonable argument could be made that the Prolift
12
                                                              12
13
        Q Dyspareunia --
                                                              13
                                                                  should not have been marketed based on the severe
14
       A -- was high. It was high in this study.
                                                              14
                                                                  complications that they're aware of, would that be
        Q Dyspareunia -- you would agree with me
                                                              15
                                                                  significant to you?
15
16
    postoperative dyspareunia after Prolift surgery is
                                                              16
                                                                         MR. ISMAIL: Objection to form.
    high; that's documented in the literature, including
                                                              17
17
                                                                         THE WITNESS: No.
18
    your own article, correct?
                                                              18
                                                                         MR. SLATER: Let's pull out Exhibit 4,
19
           MR. ISMAIL: Objection to form.
                                                              19
                                                                      if we could, Jonathan, 4 and 5.
20
           THE WITNESS: That is not correct.
                                                              20
                                                                         (Discussion off the written record.)
21
        Q (By Mr. Slater) Well, in your abstract, you
                                                              21
                                                                         MR. SLATER: March of 2008.
22
    called it a high de novo dyspareunia rate, right?
                                                              22
                                                                         THE WITNESS: Yes.
23
       A That's correct, 24 percent is high.
                                                              23
                                                                      Q (By Mr. Slater) Do you see that?
24
        Q You just said it -- and you just said a
                                                              24
                                                                      A I do.
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Page 186 Page 188 Q Okay. Let's look at the first email in the 1 it with Ethicon; and as you can see, they were -- they 1 2 middle of the page. Someone -- a Mel Seitz wrote an were talking about it internally and getting ready for 2 3 email to you. Do you remember who Mel Seitz is? 3 that meeting on their end. Do you see that? 4 A I don't. 4 I do. 5 Q Mel Seitz wrote to you and said, "Hi, 5 Q Why did you send your presentation to Ethicon 6 Dr. Lowman. It was great talking with you today. You 6 in advance of the presentation? 7 are a class act. Here is the info on our upcoming 7 A Because he asked for it. 8 8 cadaver lab that I mentioned today. Apparently they Q That's it? I mean, no matter what they asked 9 9 don't have the faculty nailed down yet, but I am you for, you would send them? A No. I didn't see any problem with sending 10 assuming that Vince Lucente and/or Jim Raders will be 10 involved. If you are able to attend, let me know and I 11 11 the presentation to them. 12 will get you the details as they are made available. I 12 Q Do you remember sending the presentation to 13 would love to get anything you are able to send me 13 Ethicon? regarding your upcoming presentation in Savannah. Good 14 14 A I don't remember that, but I don't see -- I luck on the presentation. Have a great weekend. 15 15 wouldn't see a problem doing that. So if this email Mel Seitz." Do you see that? 16 16 is, you know, real, I assume I did that. 17 A I do. 17 Q Exhibit 5, do you have that in front of 18 Q Now, the presentation in Savannah, what 18 you? That's the --19 presentation was that? 19 A Yes, I do. 20 A The one we just discussed. 20 0 -- the presentation you sent over to Ethicon. 21 Q That was the SGS presentation? 21 Uh-huh. Α 22 A Yes. 22 And if you turn forward, the -- well, Q 23 Q You wrote back to Mel Seitz on March 12, 23 rephrase. 24 2008. "It was great talking with you, Mel. I have 24 This is the rough draft of your presentation Page 187 Page 189 1 attached my abstract and a rough draft of my 1 that you shared with Ethicon in March of 2008, correct? 2 MR. ISMAIL: Objection to form. 2 presentation. Won't be able to attend the cadaver lab, 3 THE WITNESS: I'm sorry, could you ask but keep me posted on upcoming events." You see what 4 you wrote there? 4 the question again? 5 5 Q (By Mr. Slater) The way this was produced to A I do. 6 Q So you sent Mel Seitz your abstract and a 6 us by Ethicon --7 rough draft of your presentation, right? 7 A Uh-huh. 8 Q -- this was the attachment to the email that 8 A It looks like I did, uh-huh. 9 is apparently the rough draft of your presentation. Q So you felt it was appropriate to share a 9 10 presentation you were going to make at a medical 10 And the Bates number of it, for the record, is ETH.MESH.00006815. That's the placeholder Bates number 11 meeting of a medical society with an Ethicon corporate 11 representative, someone who worked for Ethicon, you 12 for this presentation. 12 Do you recognize this as the PowerPoint for 13 felt it was appropriate to share your presentation with 13 him in advance, correct? 14 the presentation you gave to SGS on your study of the 14 15 A That's correct. 15 Prolift and dyspareunia? 16 Q That's what it says here, right? 16 MR. ISMAIL: Objection to form. 17 THE WITNESS: This looks like the data 17 A That's correct. Jon Salyer, "Hey Scott. Here is the 18 that I would have presented. 18 PowerPoint that Dr. Joye Lowman, Doug Hale's senior Q (By Mr. Slater) And if you turn forward 19 19 fellow, is presenting next month in Savannah on Prolift 20 about five pages, there's a "Methods" section. 20 and dyspareunia. Let me know if you have any A Uh-huh, yes, I'm here. 21 21 questions. Mel." Do you see that? 22 Q And you indicate on that that de novo 22 23 A I do. 23 dyspareunia rate was calculated by chart review. Do 24 So you sent this presentation over and shared 24 you see that?

Page 190 Page 192 1 A Yes. mesh augmentation that are less common are mesh 1 2 Q And then you say that, "Patient satisfaction 2 extrusion and mesh contraction." Do you see that? 3 was assessed anonymously with a seven-item dyspareunia 3 A That's correct. specific questionnaire." I want to stop there. 4 4 Do you know what the mesh contraction rate is Q 5 A Okay. 5 that was found by the French doctors who developed the 6 6 Q That questionnaire, the seven-item Prolift, in their studies? 7 questionnaire, was not a validated questionnaire, 7 A I don't. Actually, I don't know if you're 8 correct? 8 referring to the original studies or if you're 9 9 referring to their meta-analysis. I am familiar with A That's correct. 10 Q Patient satisfaction, you say here, was also 10 the data from the meta-analysis. assessed by a validated condition-specific Q You think that -- what meta-analysis? You're 11 11 questionnaire, the PISQ-12, right? saying that the French doctors who developed the 12 12 13 A Yes. 13 Prolift did a meta-analysis? Q What you don't disclose is that de novo 14 14 A Jacquetin and Cosson, yes. dyspareunia was also assessed by the PISQ-12. You 15 15 Q The meta-analysis of what? don't say that, correct? 16 Of outcomes with vaginal mesh procedures. 16 Α 17 A I don't see that stated here, no. 17 Q Limited to the Prolift? 18 Q And then on the next page, you go through the 18 A They did a subanalysis with Prolifts, yes. 19 results. 19 Q That's -- what I'm asking is this: Are you 20 20 A Uh-huh. familiar with the rates of contraction that were 21 Q And you have the dyspareunia rate of 16.7 21 reported by the French doctors who developed the percent, which is based on the chart review, correct? 22 Prolift in their various studies? 22 23 A That's correct. 23 MR. ISMAIL: Objection to form. 24 Q And that's what you presented to SGS, the 24 THE WITNESS: Yeah. Page 191 Page 193 16.7 percent, correct? 1 Q (By Mr. Slater) For example, are you aware 1 2 2 they reported 17 percent shrinkage or contraction with Α Yes. 3 And that's what you published in the American 3 their initial sets of Prolift patients? Journal of Obstetrics and Gynecology, 16.7 percent, 4 4 A I don't know what they reported with their 5 5 initial sets of Prolift patients, no. correct? 6 A That's correct. 6 Q You talk a lot in your report about the fact 7 Q Okay, let's go back to your report now. 7 that one can get dyspareunia after Prolift surgery and one can have dyspareunia after a native tissue repair 8 Α 8 9 with sutures. You talk about that in your report, 9 And let's turn -- let's figure out where we want to pick up. Give me one second. See what I've 10 right? 10 11 covered. 11 A Yes. 12 Q If one has dyspareunia after a Prolift 12 Okay, I have one question before I get into 13 this. You'll agree with me that abdominal 13 surgery and it's related to the mesh, the cause of that sacrocolpopexy is the gold standard treatment for the dyspareunia is different than what the cause would be 14 14 treatment of prolapse, correct? with a nonmesh suture procedure because there would be 15 15 16 A For the treatment of apical prolapse, yes. 16 no mesh there; would you agree with that? Q I'm just flipping through your report. Give MR. ISMAIL: Objection to form. 17 17 me a second. I'm trying to shorten things here. 18 THE WITNESS: If the cause of -- could 18 A Okay. 19 you restate the question, please? I'm sorry. 19 20 MR. SLATER: Sure. 20 Okay, let's turn to page 13, if you could. Q 21 Q (By Mr. Slater) If somebody has a Prolift 21 Α surgery and has dyspareunia after it, related to the 22 On page 13, there's a paragraph that starts 22 in the middle of the page, and if you read down, 23 Prolift mesh --23 there's a list, it says, "Other risks associated with 24 A Uh-huh. 24

Page 194 Page 196 Q -- then by definition the cause of that her that she has had pelvic pain and dyspareunia after 1 1 2 dyspareunia would be different than in the case of a 2 the Prolift surgery? 3 suture repair because the suture repair does not have 3 MR. ISMAIL: Objection to form. 4 THE WITNESS: I accept that. 4 mesh, correct? 5 MR. ISMAIL: Objection to form. 5 Q (By Mr. Slater) Okay. I want to ask you about the Altman study. Can you hear me? I'm going to 6 THE WITNESS: I think that's correct. 6 7 7 ask you about the Altman study from 2011, the one MR. SLATER: Okay. published in the New England Journal of Medicine. You 8 Q (By Mr. Slater) The treatment of dyspareunia 8 9 9 talk about that study quite a bit in your report, caused by Prolift mesh is different very often from the treatment of dyspareunia where there's no mesh 10 correct? 10 11 A I do. 11 involved, correct? Q That study and the results of that study are 12 A Not necessarily, no. 12 13 Q Sometimes the treatment is different, for 13 very important to you in forming your opinions in this example, if mesh has to be removed or revised, correct? case; is that true? 14 14 15 A If mesh has to be removed or revised, that's 15 A That's true. obviously different than a -- than what you would do 16 Q Do you consider the Altman study to basically 16 be the landmark study with regard to the Prolift? with a traditional repair where there's no mesh, yeah. 17 17 18 Q Ms. Hammons did not have recurrent prolapse 18 MR. ISMAIL: Objection to form. at the time that Dr. Baker put the Prolift in, correct? THE WITNESS: I consider it to be one of 19 19 20 20 MR. ISMAIL: Objection to form. the landmark studies, not just with regard to 21 THE WITNESS: Not that I'm aware of. 21 the Prolift, but with pelvic organ prolapse 22 22 repair, period. (By Mr. Slater) The operation by Dr. Baker 23 to place the Prolift was Ms. Hammons' primary prolapse 23 Q (By Mr. Slater) Have you seen -- well, 24 repair, her first one, correct? 24 rephrase. Page 195 Page 197 1 Α That's correct. 1 Have you seen any information about the 2 2 Q Ms. Hammons was not complaining of any pelvic depositions that were taken of the editors of the 3 pain or dyspareunia at the time that she had the 3 New England Journal of Medicine about the Altman study? Prolift placed in her body, correct? 4 A No. 4 5 5 A She was not complaining of that to Dr. Baker, Deposed? 6 that's correct. 6 A I missed your question. 7 Q Well, when you say she wasn't complaining to 7 Depositions of the editor-in-chief and Dr. Baker, are you contending that she had pelvic pain 8 executive editor of the New England Journal of Medicine 8 9 or dyspareunia before the Prolift was placed? 9 were taken with regard to the Altman study? 10 A No, I'm not. I'm just saying that what I 10 A I'm sorry, I still missed the first part of 11 have to go on is what she reported to Dr. Baker. 11 your question. Q And you have no reason to believe that 12 Q Are you -- can you hear me now? 12 A I can hear you now. 13 Patricia Hammons had pelvic pain or dyspareunia before 13 the Prolift was placed, correct? 14 Q Okay. All right, I'll just talk, because 14 when you talk, it brings the mic back to your room, so 15 That's correct. 15 16 Q Report that she has pelvic pain and 16 let me just finish. dyspareunia after the Prolift? 17 17 A Okay. 18 A You -- I missed half of that question. 18 Q Are you aware that Dr. Curfman, the executive Q Opinions in this case, do you accept Patricia editor of the New England Journal of Medicine, and 19 19 Hammons' report -- you're not hearing me? 20 Dr. Drazen, the editor-in-chief of the New England 20 A No. I missed the first half of that one too. Journal of Medicine, had their depositions taken with 21 21 regard to the Altman study? 22 Q Okay. I'll start over. In forming your 22 opinions in this case, do you accept Ms. Hammons' 23 A I'm not aware of that. 23 24 report to her physicians and those who have examined 24 Are you aware -- let me ask you this: Are

Page 198 Page 200 you aware of any issues with the POP-Q measurements MR. ISMAIL: Objection to form. 1 2 that were relied on to give the anatomic recurrence 2 THE WITNESS: That's correct. 3 results that are relied on in the Altman study? 3 (By Mr. Slater) Let me ask you this: When 4 4 the authors of the Altman study evaluated the data A I'm not. 5 Q Are you aware of what involvement Ethicon had 5 based on functional outcomes, they found that the 6 with the study design, the analysis or interpretation 6 Prolift was no better than anterior colporrhaphy in 7 of the data, or the writing or editing of the 7 terms of the functional outcomes reported by the manuscript that was published? Do you know anything 8 8 patients, correct? 9 about Ethicon's involvement in that at all? 9 A I think that's incorrect, but I -- if you --10 Α No. 10 do you have that article by any chance? O I don't have the article. 11 Q As you sit here now, do you have any 11 knowledge that Ethicon was involved in the study 12 12 A Okay. design, the interpretation of the data, or the writing 13 Q Let me ask you this: From a statistical --13 or editing of the manuscript, do you have any knowledge 14 14 My recollection is that's incorrect. of that occurring? 15 15 I'm not asking for the actual pure, specific numbers. This is what I'm asking you: In the manner 16 Α No. 16 in which people evaluate the data --17 Is it your assumption that Ethicon had no 17 Q 18 involvement with the Altman study other than providing 18 A Uh-huh. 19 19 Q -- and the way the authors evaluated the data 20 A That's my understanding, yes. 20 in their conclusion --21 Q If Ethicon, in fact, had involvement in 21 A Uh-huh. editing the article and, in fact, if at least four 22 -- it was found that from a statistical 22 23 Ethicon employees had involvement in editing the 23 perspective, the functional outcomes between the article, and if Ethicon was involved in the study 24 Prolift and anterior colporrhaphy were essentially the Page 199 Page 201 1 design and the interpretation of the results, that 1 same, correct? 2 2 information could impact on your evaluation of the You're talking about the number of 7 and 2? 3 data, right? 3 No, I'm talking about the functional outcomes 4 MR. ISMAIL: Objection to form. 4 for the people after the surgery. 5 5 THE WITNESS: No. A That's incorrect. 6 Q (By Mr. Slater) Let me ask you this: If 6 Q Fine. Thank you. 7 Ethicon made edits to the article such that they would 7 Do you know -- well, let me ask you this: Do 8 you know anything about whether or not the authors of 8 make the dyspareunia rates look more acceptable, lower, 9 would that be of any concern to you? 9 the Altman study had financial consulting relationships 10 MR. ISMAIL: Objection to form. 10 with Ethicon? 11 THE WITNESS: I'm not sure how you would 11 A I don't. edit numbers. I mean, the numbers really are 12 12 Q Does it matter to you? 13 the numbers, which is what I based my 13 Α 14 assessment on. 14 Q With the concept of financial bias in 15 15 Q (By Mr. Slater) Let me ask you this: The clinical studies? 16 de novo dyspareunia rate with the Prolift was 7 percent 16 MR. ISMAIL: Restate, please. 17 17 and the de novo dyspareunia rate with anterior MR. SLATER: Sure. colporrhaphy was 2 percent. That's what was reported, 18 Q (By Mr. Slater) Are you familiar -- let me 18 correct? ask this: Are you familiar with the concept of 19 19 20 financial bias in clinical studies? 20 A That's correct. 21 21 Q So let me ask you this: The de novo A I've never heard that term used before, no. 22 dyspareunia rate was more than three times higher with 22 Q Let me ask you this question: With regard to 23 the Prolift than with native tissue suture repair, 23 the various studies that have evaluated the Prolift, in 24 correct? 24 evaluating them, did you look to whether or not the

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Page 202
                                                                                                                Page 204
    people who performed the studies and wrote the
                                                                 And I'm not really being facetious, but I want to
1
                                                             1
    articles, whether they had financial relationships with
                                                             2
                                                                 understand something. It could save me a lot of
2
    Ethicon? Was that something you considered at all?
                                                                 questions. Is there anything I could tell you about
3
                                                             3
                                                                 the Prolift or people who know about the Prolift that
           MR. ISMAIL: Objection to form.
                                                             4
4
5
           THE WITNESS: No.
                                                             5
                                                                 would -- that would impact any of the opinions you've
                                                             6
6
        Q (By Mr. Slater) Let me ask you this: On
                                                                 given in this report?
7
    page 24 of your report, you say that, "The fact that
                                                             7
                                                                        MR. ISMAIL: Objection to form.
    studies selected the Prolift to be studied supports
                                                             8
8
                                                                        THE WITNESS: I -- that's a difficult
9
                                                             9
    that the Prolift is not just an acceptable procedure,
                                                                     question for me to answer. I don't think so.
10
    but it is arguably the procedure of choice, i.e., the
                                                            10
                                                                     Q (By Mr. Slater) Let me ask you this
    industry standard for trocar-guided mesh augmented
                                                                 question: With Patricia Hammons, after the surgery, in
11
                                                            11
    prolapse repair." You made that statement, correct?
                                                                 the postoperative period when she was -- in her acute
12
                                                            12
13
        A That's correct.
                                                            13
                                                                 healing phase, she healed fine, right?
                                                                        MR. ISMAIL: Which operation?
14
        Q Do you know of anybody that's ever published
                                                            14
    in an article that's peer-reviewed that the Prolift was
                                                                        MR. SLATER: That's a good question,
15
                                                            15
    considered to be the industry standard for these types
                                                            16
                                                                    actually. Thank you.
16
                                                                        MR. ISMAIL: You're welcome.
    of repairs?
                                                            17
17
18
        A No. That's my opinion.
                                                            18
                                                                     Q (By Mr. Slater) After the Prolift was
                                                                 implanted, Ms. Hammons' healing was uneventful, she
19
        Q Okay. Let me ask you this: Do you know
                                                            19
    whether or not doctors who were using the Prolift
                                                                 healed fine from that surgery, correct?
20
                                                            20
                                                                        MR. ISMAIL: Objection to form.
21
    continued to use it with the same frequency as the
                                                            21
    years went on or whether or not the use of the Prolift
                                                            22
                                                                        THE WITNESS: Other than having some
22
23
    went down? Do you have any idea?
                                                            23
                                                                     scar tissue or some tenderness noted at the
24
           MR. ISMAIL: Objection to form.
                                                            24
                                                                     vaginal cuff, yes.
                                                   Page 203
                                                                                                                Page 205
1
           THE WITNESS: No.
                                                             1
                                                                     Q (By Mr. Slater) Well, let me ask you this:
2
        Q (By Mr. Slater) Do you know what
                                                             2
                                                                 The -- you said she had scar tissue or tenderness at
    Dr. Lucente's -- let me ask you this: Dr. Lucente is
3
                                                             3
                                                                 the vaginal cuff?
4
    somebody you have great respect for, correct?
                                                             4
                                                                    A Uh-huh.
                                                             5
5
        A Correct.
                                                                    Q When was that first noted, how long after the
6
        Q Do you know what Dr. Lucente's opinion was as
                                                             6
                                                                 surgery?
7
    between whether or not one should use the Prolift or
                                                             7
                                                                    A Eleven weeks.
    the Prolift+M based on safety considerations?
                                                             8
                                                                     O Okay. Well, let me ask you this: One can
8
9
                                                             9
                                                                 have normal healing and have some discomfort at the
        A I don't.
10
        Q Do you know what Dr. Lucente's opinion was as
                                                            10
                                                                 vaginal cuff after a Prolift surgery, correct?
    between the Prolift and Prolift+M in terms of what was
                                                                    A What do you mean by "normal healing"?
11
                                                            11
    more compatible with a female's tissue?
                                                            12
                                                                    Q Healing without any complications.
12
13
        A I don't.
                                                            13
                                                                        MR. ISMAIL: Restate, please.
                                                            14
                                                                        MR. SLATER: Sure.
14
        Q Significance to you in forming your opinions
                                                            15
                                                                     Q (By Mr. Slater) Do you consider that the
15
    in this case?
16
           MR. ISMAIL: Restate, please.
                                                            16
                                                                 discomfort and tenderness at the vaginal cuff --
17
           MR. SLATER: Sure.
                                                            17
                                                                 rephrase.
18
        Q (By Mr. Slater) Would Dr. Lucente's opinions
                                                            18
                                                                        Do you consider the scarring and the
    about the Prolift M versus the Prolift be of any
                                                                 tenderness at the vaginal cuff 11 weeks after the
19
                                                            19
    significance to you in forming your opinions in this
                                                            20
                                                                 Prolift to be due to any complication?
20
21
    case?
                                                            21
22
           MR. ISMAIL: Objection to form.
                                                            22
                                                                    Q Okay. Let me ask you this: Did you see any
23
           THE WITNESS: No.
                                                                 indication that Ms. Hammons did not heal normally after
                                                            23
                                                                 the Prolift was implanted?
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Q (By Mr. Slater) Let me ask you this, Doctor.

24

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11

12

1 A No.

Q So let me ask you this: So even though
Ms. Hammons was a smoker at the time of the Prolift,
her healing after the Prolift surgery was not impacted
by that, correct?

6 A Not by anything that we could see on exam, 7 no.

8 Q All right. Let me ask you something else. 9 In your report, you indicate that Ms. Hammons had a 10 Stage 4 prolapse. You say that, right?

A Yeah.

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12

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Q Okay. She never had a validated measure done of her prolapse before Dr. Baker operated on her and placed the Prolift, correct?

MR. ISMAIL: Objection to form.

16 THE WITNESS: I'm not sure what you mean by that.

18 Q (By Mr. Slater) Let me ask you this: Did

19 Dr. Baker calculate POP-Q measurements before he placed20 the Prolift?

21 A No.

22 Q Okay. What measurement criteria did

23 Dr. Baker utilize, what validated measurement criteria

24 did he utilize preoperatively to measure the prolapse

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Walker staging. It's not necessarily as simple as thebladder being completely outside of the vagina.

3 There's specific criteria for that.

Q Okay, fine. Let me ask you this: Did
Dr. Baker reference any criteria, such as POP-Q, ICS,
or Baden-Walker, in justifying his description of the

7 prolapse in terms of staging?

A When practitioners are using the Baden and Walker system, it's just graded. There are no numbers that are documented. It's Grade 1, Grade 2, Grade 3, or Grade 4. He assessed her prolapse as Grade 4. I would assume he was using the Baden-Walker system.

13 Q Let me ask you this: What is it about 14 Dr. Baker's -- well, let me ask you this: In saying 15 it's a Stage 4 prolapse, are you applying the 16 Baden-Walker system?

17 A Yes.

18 Q And what is the criteria for a Stage 4 19 prolapse under Baden-Walker?

A Greater than halfway outside of the hymen. So Grade 1 is halfway to the hymen, Grade 2 is at the

22 hymen, Grade 3 is halfway beyond, and I'm talking about

23 vaginal length, and Grade 4 is greater than halfway

24 beyond. So that's all in reference to the hymen and

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14

before the Prolift was implanted?

A I don't know. No one ever asked him that, from my review of his deposition.

Q Okay. Dr. Baker's comments on the -- on the prolapse that Ms. Hammons exhibited, one could interpret that to be anywhere from a Stage 2 to a Stage 3 and you call it a Stage 4, right?

MR. ISMAIL: Objection to form.

THE WITNESS: I disagree.

MR. SLATER: Okay.

Q (By Mr. Slater) Well, let me ask you this question: Why do you call it a Stage 4 prolapse preoperatively? What is it about Dr. Baker's exam that tells you it's a Stage 4?

A Because he called it a Stage 4, and I would assume that somebody that operates on patients that have pelvic organ prolapse understand what Stage 4 prolapse is, regardless of whether or not they can assess POP-Q measurements.

Q All right. Let me ask you: Is a Stage 4 where the bladder would be completely out of the vagina?

A A Stage 4 -- you want me to just -- there's specific definitions for ICS grading and for Baden and

1 the vaginal length.

Q Well, let me ask you this: When you say greater than halfway beyond the hymen," what is greater than halfway beyond the hymen?

A Total vaginal length.

Q Are we talking about the location of the bladder?

A No, that's what I'm saying, it's not that simple. It's not just about the location of the bladder.

11 Q Well, let me ask you this: For a Stage 4 12 prolapse under Baden-Walker, where would the bladder 13 need to be to reach Stage 4 --

A It doesn't consider bladder --

15 Q -- for a cystocele?

16 A -- location. The Baden-Walker system doesn't 17 describe the bladder location. It's describing the 18 amount or length of vagina that is outside -- or in 19 relation to the hymen.

Q Ah. So it's describing the amount of the vaginal length that is everted outside the hymen; is that what you're saying?

23 A That's correct.

Q Okay. And did Dr. Baker actually make a

53 (Pages 206 to 209)

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24

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Page 210
                                                                                                                   Page 212
    finding of a particular amount of the vaginal length
                                                                  is you're just accepting Dr. Baker calling it a Stage 4
2
    that was actually everted outside the hymen? Did he
                                                                   or a Grade 4; you don't need to see any corroborating
3
    actually document that in his records?
                                                               3
                                                                   medical information to support that, right?
                                                               4
4
       A He did by calling it a Grade 4 prolapse.
                                                                         MR. ISMAIL: Objection to form.
5
    That's what he's documenting.
                                                               5
                                                                         THE WITNESS: There is corroborating
6
        Q Conclusion, but there is no clinical
                                                               6
                                                                      medical information to support that, in my
7
    documentation from which you can evaluate the basis for
                                                               7
                                                                      opinion.
    his conclusion it's a -- it's a Grade 4, correct?
8
                                                               8
                                                                      Q (By Mr. Slater) What's that?
                                                               9
9
           MR. ISMAIL: Restate, please.
                                                                          Dr. Drolet and Dr. Zipper currently assess
                                                              10
                                                                   Mrs. Hammons' prolapse as a -- I can't remember if they
10
           MR. SLATER: Sure.
                                                              11
                                                                   used POP-Q or Baden-Walker, but they say Stage 3. And
11
        Q (By Mr. Slater) Dr. Baker did not document
    data regarding his examination of the vagina such that
                                                                   currently she's asymptomatic. When she presented to
12
                                                              12
13
    you could corroborate whether or not it really is a
                                                              13
                                                                   Dr. Baker, she was symptomatic. So I would assume that
    Stage 4 or a Grade 4 under Baden-Walker, he just gave
                                                              14
                                                                   the prolapse that she had when she presented to
14
    the conclusion, correct?
                                                              15
                                                                   Dr. Baker is larger than it was when she presented and
15
16
           MR. ISMAIL: Objection to form.
                                                              16
                                                                   was evaluated by Dr. Zipper and Drolet.
17
           THE WITNESS: When you use the Baden and
                                                              17
                                                                      Q Okay. Let me ask you this: What symptoms
18
       Walker system, that grade is the objective
                                                              18
                                                                   was Ms. Hammons experiencing due to prolapse before the
19
        documentation.
                                                              19
                                                                   Prolift was put in her body?
20
        Q (By Mr. Slater) Well, let me ask you this:
                                                              20
                                                                      A From what I remember, she reported that it
21
    If you wanted to document in a chart a Grade 4 prolapse
                                                              21
                                                                   was bothersome with coughing, lifting, and with sexual
    under Baden-Walker and you wanted another doctor to be
                                                              22
                                                                   intercourse, her bulge.
22
23
    able to evaluate the basis for your conclusion, you
                                                              23
                                                                      Q Meaning that she was aware of it, she could
    could document your specific findings on examination
                                                              24
                                                                  feel it?
                                                    Page 211
                                                                                                                   Page 213
    that form the basis for your conclusion, you could do
                                                               1
                                                                           She was -- she was aware of it, right.
1
2
    that, correct?
                                                               2
                                                                          She had no pain reported, correct?
                                                                       Q
3
        A You could.
                                                               3
                                                                       Α
                                                                           She did not report --
4
                                                               4
                                                                       Q She reported no pain, correct?
        Q Dr. Baker did not do that, correct?
                                                               5
5
        A If you're asking if he documented vaginal
                                                                           She did not report pain.
6
    length and how much vaginal length was outside of the
                                                               6
                                                                           She didn't report dyspareunia either,
                                                                       Q
    vagina, no, he didn't.
7
                                                               7
                                                                   correct?
                                                               8
8
        Q Testimony from Dr. Baker explaining that he
                                                                       A She did not.
9
    understood and applied the Baden-Walker system and
                                                               9
                                                                          Let me ask you this question: If -- and I'm
10
    actually that's how he came to his finding of a
                                                              10
                                                                   asking you to draw an assumption -- if the evidence
11
    Grade 4? Did he testify to that?
                                                              11
                                                                   were to establish that she actually had a Stage 3 or
        A I missed -- I missed the first part of that
12
                                                              12
                                                                   early -- rephrase.
13
    question. I'm sorry.
                                                              13
                                                                          If the evidence were to establish that
14
        Q Sure. Sure. Do you have any information
                                                              14
                                                                   Ms. Hammons actually had a Stage 2 or early Stage 3
   from a medical record or a deposition indicating that
15
                                                                   prolapse, would that have any impact on any of your
                                                              15
16
    Dr. Baker actually applied the Baden-Walker system,
                                                              16
                                                                   opinions in this case? And I'm talking about
                                                                   pre-Prolift.
17
    evaluated the amount of vaginal length that was
                                                              17
    outside -- beyond the hymen, and utilized that
                                                              18
18
                                                                       Α
19
    information in coming to a conclusion of a Grade 4
                                                              19
                                                                          Let me ask you something, Doctor. You talk
20
    prolapse?
                                                              20
                                                                   in your article [sic] on page 31 about the "Time to
                                                                   Rethink" article, right?
21
        A That's what using that term is an indication
                                                              21
22
    of, and you don't have to physically measure the
                                                              22
                                                                       A Yes.
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MR. ISMAIL: You said your article. Do

you mean the report, Mr. Slater?

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length. You can eyeball it, if you will.

Q So the bottom line is -- the bottom line here

Page 214 Page 216 MR. SLATER: In her -- in her report on A I don't know. 1 1 2 page 31, there's a discussion of the "Time to 2 Did the authors of the article, who happen to 3 Rethink" editorial. 3 be Lucente and Murphy, write back to you when you gave your feedback? Did they respond? 4 4 THE WITNESS: Yes. 5 Q (By Mr. Slater) Okay. You know that's not a 5 A I don't remember. 6 peer-reviewed article, right? 6 Q Did you send it to them by email? 7 A I know that, yeah. 7 I believe so. Q You say that, "The Pelvic Surgeons Network, 8 8 Q Do you still have that email? 9 consisting of over 600 pelvic surgeons, including 9 Probably not. Α myself, conducted an analysis of available data, 10 10 Do you have the email you received from them including efficacy and potential complications with with the article and the -- and the petition attached 11 11 regard to transvaginal mesh placement for prolapse 12 12 to it? 13 treatment." That's what you wrote, right? 13 A Probably not, no. 14 A That's correct. MR. SLATER: All right. Well, we'll ask 14 15 Q Have you read -- well, let me ask you this: 15 for production of those items, the email with Do you know where the name Pelvic Surgeons Network came regard to "Time to Rethink" and any email 16 16 from Dr. Lowman back to Lucente and Murphy, 17 from? 17 18 A I don't. 18 if she has it. 19 19 Q The 600 surgeons conducted an analysis of MR. ISMAIL: We'll take it under 20 20 available data, are you saying you participated in some advisement. 21 sort of a scientific study of data? 21 Q (By Mr. Slater) Would you have used your 22 MR. ISMAIL: Restate, please. 22 work -- Dr. Lowman --23 Q (By Mr. Slater) Are you saying -- when you 23 A Yes. say that 600 pelvic surgeons, including yourself, 24 Q -- what computer were you using at the time? Page 215 Page 217 conducted an analysis of available data, are you saying 1 Α 2012? I don't know. 1 2 an actual scientific analysis was undertaken? 2 You were in Atlanta at your current practice, Q 3 A I'm not sure what you mean by that. Did we 3 right? 4 generate a scientific paper, is that the question or --4 A I was, uh-huh. 5 5 I'm --Q Has the computer system in your office been 6 Q Yeah, let's start with that question. 6 changed since that time? 7 A We did not generate a scientific paper, but 7 A My office has changed since that time. Before I got a partner, before we hired Dr. Saguan, I 8 we did analyze current data. 8 9 Q When you say -- let me ask you this: When 9 was floating throughout the region, so I was using 10 you say "we," did you participate in writing that 10 different computers. It wasn't until either late 2012 11 editorial? 11 or 2013, I believe, that I had a stationary office or I 12 A No. 12 was in one location most of the time. 13 Q All that happened was it was circulated to a 13 Q Well, you had an email account, right, for bunch of doctors and they signed the petition at the your -- for your practice? Is that what you would have 14 14 15 15 end, right? used for these emails? 16 A Yes, after reviewing, giving feedback, yes. 16 A That's correct. Either that or my personal account. I don't know which one it was. 17 Q Let me ask you: You gave feedback on the 17 article? 18 18 Q Do you have the same email accounts, your 19 A Yes. 19 professional and private ones, are they still the same? Q Did that impact the writing of the article? 20 They are. 20 Α Did the language change based on your feedback? You'd be able to go look into your old emails 21 21 22 22 and see if you still have those, right? Α No. 23 Q Do you know if anybody else gave feedback 23 MR. ISMAIL: Objection to form. 24 besides you? 24 THE WITNESS: I can look.

Page 218 Page 220 causes that contributed to this? MR. SLATER: Okay. 1 1 2 (By Mr. Slater) By the way, one other 2 A Yes. 3 question. The "Time to Rethink" article was not 3 Q Let me ask you this question: You refer to 4 4 limited to discussing the Prolift, was it? mesh that had been placed on excessive tension. When 5 No, it wasn't. 5 mesh is on excessive tension, are you aware that that 6 "Think" article is talking about mesh surgery 6 can increase the risk of scar plating and contraction? Q 7 7 A I'm aware that that can cause pain. I'm not in general, right? 8 A That's correct. 8 aware that it can cause scar plating. 9 9 Q Well, let me ask you this: Do you have an Q And let me ask you this: The ultimate understanding of what happens to the pores in the 10 conclusion of that article was don't ban mesh because 10 11 Prolift when it's placed on excessive tension? 11 there are some doctors who are skilled enough to use it 12 12 in some patients who it would be appropriate to use the A I don't. mesh with if you have the right doctor; fair statement? 13 Let me ask you this question: When 13 No. There was never --Dr. Zipper examined Ms. Hammons, he found that she was 14 14 15 having -- she had tenderness on the exam and he 15 Q Okay. attributed that to the Prolift, correct? 16 A -- no ban of mesh. 16 17 Q Well, wasn't one of the concerns in the 17 A Yes. 18 article that mesh was on the verge of -- people were 18 Q Okay. That's consistent with the findings by 19 talking about banning it and that's why this article 19 Dr. Heit, correct? 20 20 was written? MR. ISMAIL: Objection to form. 21 21 A No. THE WITNESS: He -- Dr. Heit, my 22 22 impression of Dr. Heit's exam was that he Do you know that the FDA was considering Q 23 banning mesh kits like the Prolift? 23 felt that she had pain at the site of rolled 24 MR. ISMAIL: Objection to form. 24 and bunched mesh. Page 219 Page 221 1 THE WITNESS: I did -- I was not aware 1 Q (By Mr. Slater) I want to understand one 2 of that. 2 thing. You seem to suggest that if -- that the rolling 3 Q (By Mr. Slater) Are you aware up till the 3 or -- well, let me ask you this: You say rolling or present whether the FDA was considering -- well, let me bunching of the mesh. Am I correct that what you're 4 5 ask you this: You don't know anything about the 5 saying is you're basically talking about the same interaction between the FDA and Ethicon about the 6 6 thing, whether it was rolled or bunched, you're saying 7 Prolift, correct? 7 that's -- it's the same thing to you? A Not exactly, but I don't think distinguishing 8 A Correct. 8 9 9 Q Let me ask you to -- let me just get to this. them is important in terms of the pathology. Okay, if you could, turn to page 33 of your report, 10 Q Okay. The important thing is whether the 10 11 please. 11 mesh is laying flat or whether it's bunched up or folded or clumped together, that's a bad thing, right? 12 A Okay. I'm here. 12 13 Q Okay. On page 33, towards the bottom, about 13 That's correct. five lines up, your report says, "It is my opinion that 14 When the mesh is bunched up, for example, 14 15 Ms. Hammons' dyspareunia was multifactorial and was due 15 that can increase the risk for complications, correct? 16 to a combination of a shortened vagina, scarring or 16 That's correct. narrowing from a posterior repair, vaginal atrophy, and And a doctor can follow the Prolift 17 17 Q 18 rolled or bunched mesh and/or mesh that had been placed technique, follow the technique in the IFU and the 18 on excessive tension." Do you see that? 19 19 surgical guide, and the mesh can still end up bunched, 20 A I do. 20 that can happen, correct? 21 MR. ISMAIL: Objection to form. Q And you stand by that opinion today? 21 A I do. 22 22 THE WITNESS: I don't think so. 23 23 Q (By Mr. Slater) Do you think that Q When you say that the dyspareunia was

Dr. Jacquetin and Velemir knew how to do the Prolift

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multifactorial, are you saying that there were multiple

Page 222 Page 224 procedure? been my experience in clinical practice. 1 1 2 2 Q (By Mr. Slater) Your experience is 150 A Yes. 3 Prolift procedures, right? 3 O You read the Velemir article. You cited it 4 A That's correct. 4 in your report, right? 5 A Yes. 5 Okay. Ethicon, you would agree with me, 6 Q Did you see the findings that 89 percent of 6 probably has a lot more information than you do about 7 the anterior Prolifts had either moderate or severe 7 what happens with the Prolift in the human body, 8 contraction? 8 correct? 9 9 MR. ISMAIL: Objection to form. MR. ISMAIL: Objection to form. THE WITNESS: I don't remember that 10 10 THE WITNESS: I would say that I think -- it depends on who you're talking 11 11 12 Q (By Mr. Slater) Did you look in the Velemir 12 about at Ethicon. article at the ultrasound images showing that the mesh Q (By Mr. Slater) How about the medical 13 13 was bunched up and in an irregular shape? affairs directors? How about the medical affairs 14 14 A I don't remember them describing that, that 15 15 directors? it was bunched and irregular. 16 MR. ISMAIL: Objection to form. 16 THE WITNESS: The medical affairs 17 Q Seeing those pictures of the ultrasounds in 17 18 the article? 18 directors? 19 MR. ISMAIL: Restate, please. 19 Q (By Mr. Slater) Do you know what a medical 20 Q (By Mr. Slater) Do you remember seeing the 20 affairs director is? pictures of the mesh on ultrasound in the Velemir 21 21 A I think I have a good idea. I don't think 22 22 that administrators would have a better idea of what article? 23 A I don't remember the pictures specifically. 23 goes on with the Prolift than surgeons. I do believe 24 Q You say here that Dr. Baker, from your 24 that Ethicon works --Page 223 Page 225 perspective, was an appropriate surgeon and fully 1 Q Okay. 1 2 qualified and skilled to perform the Prolift procedure, 2 -- closely with surgeons. I think those 3 correct? 3 surgeons might have more information than me. 4 A Yes. 4 Q Is it -- is it your -- okay. Is it your 5 Q You also say -- rephrase. 5 understanding that the medical affairs directors at 6 You say in your report that the rolling or 6 Ethicon, even though you're not sure who they are, that 7 bunching of mesh after the Prolift in this case was 7 they're administrators? Is that what you said? most likely due to improper technique and implantation. 8 8 Okay. 9 You say that in your report, right? 9 0 Their backgrounds or qualifications, right? 10 A That's part of it, yes. 10 I'm sorry, could you repeat that? 11 Q It's also possible that Dr. Baker did do the 11 Q You don't know the background or -- sure. procedure correctly and the mesh ended up bunched just You don't know the background or qualifications of any 12 12 because of the nature of the Prolift and the fact that 13 13 of the medical affairs directors at Ethicon, right? in some women, the mesh bunches up just because of the 14 A I don't. 14 way the procedure is performed in all patients, that 15 15 O Let me ask you a couple questions about the 16 can happen, are you aware of that? 16 warnings. You read Dr. Baker's deposition, correct? 17 17 A No. A Yes. 18 O Okay. If Ethicon thinks that a doctor can 18 Q And you saw there were some things that he follow the procedure, do everything correctly, and the said he was not aware of when he was using the Prolift? 19 19 mesh can still be bunched up, would you defer to 20 20 A Yes. Ethicon, the people who developed and sell the device, 21 21 MR. ISMAIL: Objection to form. or would you say, "No, I disagree with Ethicon"? 22 22 Q (By Mr. Slater) Okay. Well, let me ask you: 23 MR. ISMAIL: Objection to form. The things he said he did not know, were those things 23 24 THE WITNESS: I would say that has not 24 that you knew?

Page 226 Page 228 MR. ISMAIL: Objection to form. 1 Gynemesh PS or the Prolift, you've never looked at 1 2 THE WITNESS: Could you be more 2 them, right? 3 3 specific? Α That's correct. 4 Q (By Mr. Slater) All right, let me ask you 4 0 You've never looked at the protocols for the 5 this question: Is it your understanding that when the 5 Gynemesh PS or the TVM studies, right? Prolift is in the body, that it creates a chronic 6 6 MR. ISMAIL: Objection to form. 7 inflammatory reaction that in some women can be severe? 7 THE WITNESS: That's correct. Do you -- do you believe that to be true? 8 8 MR. SLATER: All right, I think we're at 9 A I've not seen any evidence of that, no. 9 one minute on this tape, so let's change the Q Do you -- so you feel that doesn't happen 10 10 tape and I'm going to -- Jonathan, if we 11 based on your experience, correct? could, maybe if you could just give me a call 11 12 A Correct. on my -- on the cell or if I can call you. I 12 13 O And that's your assumption in forming your just want to ask you a question and then I'm 13 opinions, correct? 14 14 getting towards the end, guys. 15 MR. ISMAIL: Objection to form. 15 (Discussion off the written record.) THE WITNESS: That's correct. 16 THE VIDEOGRAPHER: We are now going off 16 17 Q (By Mr. Slater) Let me ask you about 17 the video record. The time is -- hang on. 18 something. On the bottom of page 56, you say, "The 18 We are now going off the video record. The professional education authored by Ethicon has been 19 time is currently 4:38 p.m. 19 more than adequate, but exceptional, in my opinion." 20 20 (Recess taken.) You say that in your report, correct? 21 21 THE VIDEOGRAPHER: We are now back on 22 A That's correct. 22 the video record with Tape No. 5. The time 23 Q You never attended the professional education 23 is currently 4:53 p.m. authored by Ethicon, we established that earlier, or if 24 24 Q (By Mr. Slater) Doctor, in front of you is Page 227 Page 229 you did, you can't remember doing so, right? 1 Exhibit 8, and it looks like you had sent an email --1 2 2

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MR. ISMAIL: Objection to form. 3 THE WITNESS: I don't remember attending 4 proctorships or dinners where we did 5 surgeries or cadaver labs afterwards. But 6 what I'm referencing is their educational 7 literature. 8 (By Mr. Slater) The educational -- rephrase. 9 You're referring there to the educational 10 literature that you saw after you were retained as an 11 expert and they sent some of that stuff to you, 12 correct?

A Yes, that's part of it.

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Q Okay. Did you go through the PowerPoints for professional education that they sent you to determine whether the information in there was accurate and truthful?

A I went through those documents, yes.

Q And you were comfortable that all the data cited in the professional education decks was accurate? MR. ISMAIL: Objection to form.

THE WITNESS: That's my position, yes.

Q (By Mr. Slater) You've never looked at the underlying data for any of the prototype studies on rephrase.

Exhibit 8 looks like it's a cover sheet from your office to Ethicon making a medical information request. Do you see that?

A I do.

Q And I don't know, is that your handwriting on it or is it someone from your office?

A That's my handwriting.

10 Q And could you just read for the record, 11 because I'm not sure if I can read all the words, what you asked for on April 15, 2013? 12

A Yes. No. 1 says, "Prolift, list of all research" -- yes, "list of all" -- sometimes I have a hard time reading my own handwriting. "List of all research papers done on Prolift and a summary of the findings if you have it." And, two, "Gynemesh used in sacrocolpopexy, list of all research papers done on it and a summary of the findings."

Q Okay. Why is it you sent that request to Ethicon?

22 A I was in the process of wanting to do a outcomes assessment on the patients that -- my patients. And I wanted to try to circumvent having to

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do an exhaustive literature search and try to get thisinformation more directly.

Q And then Exhibit 9, if you could look at Exhibit 9, they show the document that you had faxed in coming in by -- I guess they call it an e-fax, and then you see the emails above where they sent your fax around. And at the top, you have Pete Hinoul saying, "I am not sure that we owe the doctor this kind of response. We are not a library service. I wonder

9 response. We are not a library service. I wonder 10 whether I can reach out and ask what his specific 11 question is." Do you see that?

12 A I see that.

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13 Q Now, this -- the emails are in 2014 after you 14 originally sent your request in in 2013, it looks like, 15 correct?

A That's what it looks like.

Q Do you know whether or not there's some error; or do you know, was it 2013 when you sent it in? MR. ISMAIL: Objection to form.

THE WITNESS: I -- it looks like from the fax that it was 2013.

the fax that it was 2013.

MR. SLATER: Okay.

Q (By Mr. Slater) Did you ever get a response

24 from Ethicon?

Page 232

Page 233

A It was hard for me to try to get IRB approval. They kept denying it, and so I ultimately gave up, and then it -- I was also guessing that it was going to be hard for me to amass a large enough cohort of patients to make it meaningful because the Prolift was withdrawn from the market.

Q You say you wanted to get IRB approval. Are you talking about you submitted a grant request to Ethicon?

A No. Institution Review Board at Kaiser.

Q Okay. So you never got that far to even make a request to Ethicon for funding or anything; you were just trying to get IRB permission from your health system?

A Right. I didn't need funding for it.

Q Okay. I'm just checking my notes really quickly. Give me a second. I'm just checking my notes, as I said.

A Okay.

Q Oh, I think you might have -- we might have your invoices here, Dr. Lowman. I'd like to mark those and confirm how much money you've been paid in this case to date.

24 A Okay.

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A No, I don't believe so.

Q Okay. Did you ever follow up with anybody from Ethicon, whether it was a sales representative or anybody, and ask if they were going to send you this information?

A I don't remember.

Q Okay. Now, if we could, can you go back to your CV that's attached to the report, please. I just have a few questions on that.

A Okay. Okay.

Q Okay. Doctor, on the second page of your CV is a list of current research activities. Do you see that?

A I do.

15 Q Okay. Are those current research activities 16 as of today?

A No. The magnesium sulfate prophylaxis is not a current research activity, nor is the long-term success rate with the Prolift.

Q The long-term success rate of the Prolift procedure, that research activity, when did that stop?

A I don't remember exactly. I'll just have to say I don't remember.

Q Why did you cease that project?

(Discussion off the written record.)

(Exhibit 24 marked for identification.)

THE WITNESS: Okay, I have them.

Q (By Mr. Slater) Okay. All right, Doctor, you told us just earlier your -- the hourly rates that you're charging. What amount have you billed for this matter so far to date?

A It is approximately 50,000 or so.

9 Q Well, the invoices that you have there, when 10 are they dated?

A One was sent on October 15th.

12 Q What's that amount?

13 A 19,600.

Q Okay. What else do you have?

15 A And the other one, the last dated hour

documentation was August 10th, and that amount was 32,400.

18 Q Okay.

MR. ISMAIL: And just so you know --

Q (By Mr. Slater) You said that --

21 MR. ISMAIL: Just one comment.

22 MR. SLATER: Yes.

23 MR. ISMAIL: The invoices reflect -- are 24 not just Hammons specific, which maybe you

Page 234 Page 236 would have gotten to and I preempted you, but preparing for the deposition, that sort of thing? 1 1 2 just so you're aware. 2 A Right. 3 MR. SLATER: No problem. I was going to 3 Q And that wouldn't include today, or would it? 4 ask that, actually. 4 A That would not include today. 5 Q (By Mr. Slater) The invoices that you just 5 Q Okay. So over a hundred hours at \$400 an read off, the one that's August 10th, that's for work 6 hour on Hammons that you haven't billed for yet? 6 7 you did up through August 10th? 7 A That's correct. 8 Q Today, which is \$600 an hour? A Yes. 8 9 Q And what's the earliest date of that work? 9 That's correct. MR. SLATER: I don't think I have any 10 A For this particular invoice? There's -- the 10 one -- the earliest date for the work on this invoice 11 11 other questions, guys. was July 20th. Oh, yeah, this would have been before MR. ISMAIL: Okay. No questions here 12 12 that one, so yeah. That's the earliest date, either. We'll reserve reading and sign. 13 13 July 20th. 14 14 Thank you very much. 15 Q 2015 we're talking about, right? 15 THE VIDEOGRAPHER: We are now going off A Right, 2015. the video record. 16 16 17 Q Okay. And it's \$32,400. Is that for the 17 MR. SLATER: Thank you very much. 18 Hammons case or for anything else? 18 THE WITNESS: Thank you. A It's for all my work through that time 19 THE VIDEOGRAPHER: We are now going off 19 the video record. The time is currently 20 period. 20 21 Q What other work are you doing --21 4:05 p.m. This is the end of Tape No. 22 A It's not just the Hammons case. 22 5 and the end of the deposition. 23 Q -- beside the Hammons? What else is there? 23 (Deposition concluded at 5:04 p.m.) 24 There was another case that I was asked to 24 Page 235 Page 237 review. 1 CERTIFICATE. 1 2 2 O What case was that? 3 THE WITNESS: I'm able to say that? STATE OF GEORGIA 3 4 MR. ISMAIL: You're allowed, yes. 4 COUNTY OF COBB 5 5 THE WITNESS: Okay. The Delacruz 6 I, MICHELLE M. BOUDREAUX, do hereby certify 6 case. that JOYE K. LOWMAN, M.D., MPH, the witness whose 7 7 Q (By Mr. Slater) Okay. Is there any way to 8 deposition is hereinbefore set forth, was duly sworn by tell me of the \$32,400 how much was for Hammons? 8 9 me and that such deposition is a true record of the 9 A No. 10 testimony given by such witness. 10 Q The next invoice dated October 15, is that 11 from your billing from August 10 forward to October 15? 11 12 I further certify that I am not related to 12 A That's correct. any of the parties to this action by blood or marriage 13 Q And that was 19,600. Is that for Hammons 13 and that I am in no way interested in the outcome of 14 only or for more than one case? 14 15 this matter. A What -- this is November. That was for more 15 16 16 than one case, too, I believe. 17 IN WITNESS WHEREOF, I have hereunto set my 17 Q In addition to Hammons, what case? 18 hand this 17th day of November 2015. 18 A The Delacruz case. 19 Q Okay. Since October 15, do you know how many 19 20 hours you've spent up through today or can you estimate MICHELLE M. BOUDREAUX, RPR 20 on this case, on Hammons? 21 21 A It's been over a hundred. I don't know 22 22 23 23 exactly. 24 24 Q Over a hundred hours reviewing materials,

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